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Supreme Court, U.S.
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No. 91-

IN THE

# Supreme Court of the United States

OCTOBER TERM, 1991

LEDERLE LABORATORIES, Division Of American Cyanamid Company,

*Petitioner*,

v.

CAROL ANN FELDMAN,

*Respondent*.

## PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF NEW JERSEY

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## QUESTION PRESENTED

Whether the Supremacy Clause prohibits a state from imposing tort liability for failure to provide a warning when (a) federal law did not allow the warning to be given without approval of a federal agency, and (b) the federal agency had explicitly disapproved the warning.

## PARTIES TO THE PROCEEDING

Petitioner is Lederle Laboratories, an unincorporated division of American Cyanamid Company. Respondent is Carol Ann Feldman. American Cyanamid Company has no parent company and only one non-wholly-owned domestic subsidiary, Applied Solar Energy Corporation.

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*Petitioner.*

v.

CAROL ANN FELDMAN,
*Respondent.*

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**PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF NEW JERSEY**

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Lederle Laboratories, a division of American Cyanamid Company, respectfully prays that a writ of certiorari issue to review the judgment of the Supreme Court of New Jersey.

## OPINIONS BELOW

The opinion of the Supreme Court of New Jersey in *Feldman v. Lederle Laboratories, a Division of American Cyanamid Co.* is reported at 125 N.J. 117, 592 A.2d 1176 (N.J. 1991); the opinion is set forth in the Appendix at 1a. The opinion of the New Jersey Superior Court, Appellate Division, is reported at 234 N.J. Super. 559, 561 A.2d 288 (N.J. Super. Ct. App. Div. 1989); it is set forth in the Appendix at 72a.

The opinions were rendered after the second trial of this case in the Superior Court, Law Division, Essex County, New Jersey. The first trial had resulted in a verdict for petitioner. The Superior Court, Appellate Division, affirmed that judgment in an opinion reported at 189 N.J. Super. 424, 460 A.2d 203 (N.J. Super. Ct. App. Div. 1983), and the Supreme Court of New Jersey reversed and remanded for a new trial in an opinion reported at 97 N.J. 429, 479 A.2d 374 (N.J. 1984).

## JURISDICTION

The judgment of the Supreme Court of New Jersey was entered on July 24, 1991. The Court's jurisdiction is invoked under 28 U.S.C. § 1257(a) (1988).

## CONSTITUTIONAL PROVISION, STATUTES, AND REGULATIONS INVOLVED IN THE CASE

U.S. Constitution, Article VI, Clause 2:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

The pertinent provisions of the applicable sections of the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-393 (1988), and of the applicable regulations of the United States Food and Drug Administration adopted pursuant to the Act, *see* 21 C.F.R. § 130.1,

*et seq.* (1963); 21 C.F.R. § 146.1, *et seq.* (1963), are set forth in the Appendix at 111a - 120a.

## STATEMENT OF THE CASE

The manufacture and distribution of prescription drugs in the United States is regulated under the FD&C Act and regulations promulgated by the Food and Drug Administration ("the FDA") under that act. These regulations provide detailed controls over the permissible "labeling" of all drug products. Under the FD&C Act, labeling is defined broadly to include "all labels and other written, printed, or graphic matter" upon the package of the drug or "accompanying such article." 21 U.S.C. § 321(m). Information that "supplements or explains" the original labeling is itself labeling, and "[n]o physical attachment one to the other is necessary." *Kordel v. United States*, 335 U.S. 345, 350 (1948).

During the time relevant to the claim asserted by respondent in this case, manufacturers of prescription drugs were not permitted to change the labeling of their products without prior FDA approval. 21 C.F.R. § 130.9(a) (1960). Under this regulation, if a labeling change were implemented without prior FDA approval, the manufacturer's new drug application could be suspended by the agency "on the grounds that it contains an untrue statement of material fact." *Id.*

Antibiotics, including the drug at issue in this case, were and still are subject to additional statutory and regulatory controls. *See* 21 U.S.C. § 357 (1988), 21 C.F.R. § 146 (1963) (currently codified at 21 C.F.R. § 430 (1991)). Before any batch of an antibiotic could be distributed lawfully, it had to be "certified," 21 U.S.C. § 357(a); if a batch were distributed without

a valid certificate, it would be deemed misbranded under the express terms of the FD&C Act, 21 U.S.C. § 352(*l*), and the manufacturer would be subject to a range of civil and criminal penalties. *See* 21 U.S.C. §§ 332(a), 333(a), 334(a)(1). A batch of an antibiotic that was initially certified by the FDA for distribution to the public with approved labeling would subsequently come to be misbranded if the "label or labeling [were] altered . . . or cease[d] to conform to any labeling requirement prescribed by the regulations." 21 C.F.R. § 146.4(b)(2) (1963). Accordingly, a manufacturer that made an unapproved change in the labeling of a certified batch of an antibiotic would be subject to a federal enforcement action for distributing a misbranded drug.[1]

Beginning in 1959, petitioner introduced to the market an antibiotic with the trade name Declomycin®, which is in the family of tetracyclines used to treat bacterial infections.[2] Pet. App. 3a. Between 1960 and 1963, when respondent was a small child, her physician-father treated her with Declomycin two or three times a year for various illnesses. *Id.* During that time, the approved label for Declomycin did not include a warning that tooth discoloration was a pos-

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[1] Although the drug and antibiotic regulations were subsequently amended to permit the addition of certain warnings to labeling without prior FDA approval, *see* 30 Fed. Reg. 993-94 (1965); 50 Fed. Reg. 7,515 (1985), those amendments were not in effect when the claim in this case arose. Even under the current regulations, once the FDA has made a determination about the use of a warning, a manufacturer does not have the freedom to ignore that determination without exposing itself to severe penalties under the FD&C Act.

[2] The generic name for the active ingredient in Declomycin is demethylchlortetracycline, a derivative of chlortetracycline.

sible side-effect of taking the antibiotic. Respondent claimed that her permanent teeth became discolored as the result of her use of Declomycin. Pet. App. 4a. Respondent claimed further that, during the period that she used the Declomycin, petitioner knew or should have known that tooth discoloration was a possible side-effect, but nevertheless failed to provide such a warning. *Id.*

After a trial in state court, the jury found that, although petitioner had no reason to know of this side-effect when respondent first ingested Declomycin, petitioner subsequently became aware of it in 1962 and, under New Jersey common law, petitioner should have provided a warning at that time. Pet. App. 2a. The jury also found that petitioner's failure to provide a timely warning was the proximate cause of respondent's injuries and awarded her damages of $300,000. *Id.*

At trial, petitioner did not deny that it was aware in November 1962 of the literature and anecdotal reports suggesting that the use of certain tetracyclines during tooth development might cause discoloration of the teeth. Petitioner's principal defense was that, despite its knowledge of these reports, petitioner was precluded by federal law from issuing any warning to treating physicians without the prior approval of the FDA and that the FDA had refused to give such approval. It was undisputed that petitioner communicated with the FDA about the possibility of a link between the use of tetracyclines and tooth discoloration once that information became available. Petitioner asked the FDA to approve a warning about tooth discoloration, but, although the FDA approved such a warning for other tetracyclines, the agency

specifically declined to do so as to Declomycin. Indeed, in April 1963, after investigating reports for several months about the link between tooth discoloration and the ingestion of tetracyclines, the FDA announced publicly that "there is no evidence to date that . . . demethylchlortetracycline[] causes the discoloration." Pet. App. 8a. The FDA's decision regarding Declomycin remained in effect until December 1963. Pet. App. 11a.

Petitioner appealed the trial court's judgment to the Appellate Division, arguing that, under the Supremacy Clause, the requirement of FDA approval of a labeling change, together with the refusal of the FDA to grant such approval, preempted any state-imposed "duty to warn." The Appellate Division agreed. Pet. App. 74a. That court held that "under certain circumstances, such as presented here, federal law may preempt a discrete issue upon which liability is predicated because compliance with State decisional law would require federal law to be violated." *Id.* The Appellate Division found that (i) the "clear wording" of the applicable regulations required petitioner to obtain the FDA's approval before adding the desired warning to its Declomycin, Pet. App. 101a, (ii) the FDA had declined to give such approval during the very time for which the jury had found that the warning should have been given by petitioner, Pet. App. 105a, and (iii) there was no contention that petitioner had failed to provide the agency with all relevant information about the drug and tooth discoloration. Pet. App. 103a.

On petition for certification, the Supreme Court of New Jersey, with one dissent, reversed and held that the FD&C Act, the labeling regulations, and FDA's

implementation of those regulations in this case did not preempt respondent's claim under state tort law. The court ruled that, "in the absence of a clear and manifest purpose to preclude the traditional workings of the tort compensation system," Pet. App. 32a, there is no reason that petitioner's "literal[]" compliance with the federal labeling regulations should render it "immune from state tort liability for injuries caused by [its] products." *Id.* The court found that there was "not a sufficient basis on which to find a direct conflict between state and federal law," *id.*, because petitioner could have avoided whatever conflict existed had it (1) refrained from marketing Declomycin, Pet. App. 38a, (2) interpreted the regulations to accommodate state tort law, discounting the risk of an FDA enforcement action, Pet. App. 35a-36a, or (3) realized that it could comply with the federal law on the condition that it pay damages to plaintiffs injured by such compliance. Pet. App. 32a.

In ruling as it did, the New Jersey Supreme Court purported to follow the reasoning of the decision of the D.C. Circuit in *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984), and expressly rejected the rulings of the Fifth and Eleventh Circuits in *Hurley v. Lederle Laboratories Division of American Cyanamid Co.*, 851 F.2d 1536, *modified*, 863 F.2d 1173 (5th Cir. 1988), and *Papas v. Upjohn Co.*, 926 F.2d 1019 (11th Cir. 1991), *petition for cert. filed*, 59 U.S.L.W. 3825 (U.S. May 29, 1991) (No. 90-1837). *See* Pet. App. 32a. The court also invoked its own decision in *Dewey v. R.J. Reynolds Tobacco Co.*, 121 N.J. 69, 577 A.2d 1239 (1990), Pet. App. 36a, 37a, a case in conflict with *Cipollone v. Liggett Group*, 893 F.2d 541 (3d. Cir. 1990), *cert.*

*granted*, 111 S.Ct. 1386 (1991), *argued*, 60 U.S.L.W. 3278 (Oct. 8, 1991), *restored to calendar for reargument*, Order List (Oct. 21, 1991).

Justice Garibaldi dissented, stating that "[t]he majority's narrow view of this case and the role of the [FDA] prevent it from understanding the untoward implications its decision could have on the health of the many members of our society other than [respondent]." Pet. App. 44a. The dissent stated that the federal labeling requirements clearly were in conflict with the duty imposed by state tort law and that the majority's assumption that "tort liability judgments do not have a profound regulatory effect on the prescription drug market is naive." Pet. App. 63a. Justice Garibaldi emphasized that "[t]he FDA cannot fulfill its role [as a promotor and protector of public health] if state courts are allowed to require certain actions by pharmaceutical manufacturers that are prohibited under federal law and that supplant, rather than supplement, the carefully-considered regulations of a federal government agency." Pet. App. 45a.

## REASONS FOR GRANTING THE PETITION

The New Jersey Supreme Court held that petitioner must pay damages for failure to provide a warning that (i) was not permitted by federal law without FDA approval and (ii) was expressly considered and disapproved by the FDA. The state court acknowledged that its ruling conflicted with decisions of two federal courts of appeals, one of which is pending on petition for a writ of certiorari.[3] It did not acknowledge that

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[3] *See Papas v. Upjohn Co.*, 926 F.2d 1019 (11th Cir.), *petition for cert. filed*, 59 U.S.L.W. 3825 (U.S. May 29, 1991) (No. 90-1837).

its ruling also conflicted with decisions of this Court interpreting the Supremacy Clause. Instead, it proposed three reasons for honoring state policy in preference to federal law, each of which would stand the Supremacy Clause on its head.

## I. THE DECISION OF THE NEW JERSEY SUPREME COURT CONFLICTS DIRECTLY WITH DECISIONS OF U.S. COURTS OF APPEALS AND THIS COURT INTERPRETING THE SUPREMACY CLAUSE.

FDA regulations did not permit petitioner to add a warning to the "label" for Declomycin without FDA approval.[4] Petitioner had in fact proposed a tooth-discoloration warning for FDA approval, which the FDA had explicitly declined to grant.[5] Nevertheless, the New Jersey Supreme Court approved a jury award of damages to respondent on the ground that petitioner had violated a state law duty to warn respondent about tooth discoloration.

The state court acknowledged that its decision conflicted with two recent decisions of U.S. courts of appeals, *Hurley v. Lederle Laboratories*, 851 F.2d 1536, *modified*, 863 F.2d 1173 (5th Cir. 1989), and *Papas v. Upjohn Co.*, 926 F.2d 1019 (11th Cir. 1991), *petition for cert. filed*, 59 U.S.L.W. 3825 (U.S. May 29, 1991) (No. 90-1837). In both cases, the courts of appeals held correctly that "failure to warn" claims are preempted where the only warnings that would satisfy the state-law duty to warn are forbidden under a federal regulatory scheme.[6]

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[4] *See supra* pages 3-4.

[5] *See supra* pages 5-6.

[6] The state court's decision also conflicts with decisions of the First, Second, and Eighth Circuits. *See Animal Legal Defense*

*Hurley* involved requirements under the FDA's regulations relating to vaccines that are essentially identical to the requirements for antibiotics at issue in this case: the FDA's labeling regulations at issue there (like the regulations here) required the FDA's prior approval of new or altered warnings. 863 F.2d at 1179 (citing 21 C.F.R. § 601.12). The court of appeals held that a "state law determination [that a drug warning was inadequate] should not be interjected to overrule the decision of the FDA. Such a procedure would place vaccine manufacturers in a position where they could not comply with both obligations." *Id.*

*Papas* involved the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y (1988), which imposes a similar requirement of federal approval of label contents, including warnings. The court of appeals held that a jury verdict that the defendant had given an inadequate warning on its pesticide was preempted by federal law, in view of the Environmental Protection Agency's prior determination that

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*Fund v. Provimi Veal Corp.*, 626 F. Supp. 278 (D. Mass.), *aff'd without opinion*, 802 F.2d 440 (1st Cir. 1986) (state consumer protection act suit challenging warning on veal products held preempted by federal regulation of meat labeling and medicated animal feeds); *Grocery Mfrs. of America, Inc. v. Gerace*, 755 F.2d 993 (2d Cir.), *aff'd mem.*, 474 U.S. 801 (1985) (compliance with state labeling requirements regarding use of term "imitation" would subject manufacturer to liability for misbranding under federal regulations and thus was preempted), *cert. denied*, 474 U.S. 820 (1985); *Cosmetic, Toiletry & Fragrance Ass'n v. State of Minnesota*, 440 F. Supp. 1216, 1223 (D. Minn. 1977), *aff'd*, 575 F.2d 1256 (8th Cir. 1978) ("when federal agencies have perceived a specific risk and have required labeling to alleviate that risk . . . a state's freedom to require other than identical labeling with respect to that risk is precluded").

the defendant's warning was adequate. *See* 926 F.2d at 1024-25.

A state-law labeling requirement that conflicts with a federal requirement is, of course, preempted. As the state court recognized here, state law is preempted when "'compliance with both federal and state regulations is a physical impossibility[.]'" Pet. App. 17a (quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963)). Even if compliance with both is not physically impossible, state law is preempted if it "'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Hillsborough County v. Automated Medical Lab., Inc.*, 471 U.S. 707, 713 (1985) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). As the state court also recognized, valid federal regulations, such as the FDA's regulations here, have the same preemptive effect as federal statutes. *See* Pet. App. 16a (citing *Hillsborough County v. Automated Medical Lab., Inc., supra*; *Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 325-26 (1981)). And as the state court acknowledged, where there is a conflict between state and federal law, the importance of the state policy is immaterial and "'the federal law must prevail.'" Pet. App. 17a-18a (quoting *Free v. Bland*, 369 U.S. 663, 666 (1962)).

Although it accurately recited the law of preemption, the state court evaded its force in this case with three arguments, each of which, on examination, subordinates federal law and policy to state law and policy in clear violation of the Supremacy Clause.

## II. EACH OF THE NEW JERSEY SUPREME COURT'S THREE WAYS OF EVADING THE FORCE OF FDA LABELING REQUIREMENTS WOULD SUBORDINATE FEDERAL LAW AND POLICY TO STATE LAW AND POLICY IN CLEAR VIOLATION OF THE SUPREMACY CLAUSE.

The state court suggested three techniques that petitioner could have used to comply with its duty to warn under state law without actually violating federal law. First, petitioner could have stopped marketing Declomycin for pediatric use, abandoning the business that subjected it to inconsistent regulatory commands. Second, the court suggested that petitioner should have tried harder to convince the FDA to change its mind. If it failed to do so, according to the court, petitioner should have ignored what the FDA had said to it, published the additional warning, and taken a chance on an enforcement action, which the court asserted was not likely to be pursued by the FDA. Third, the court said that petitioner could always comply with the federal regulations, omit the warning imposed by the state tort law, and pay damages to state plaintiffs. *See* Statement of Case, *supra*, at 7. Each of these "solutions" does indeed show that, in a literal sense, it was not "physically impossible" to avoid violating either federal or state law, but each of them rides roughshod over federal policy to promote the sale of safe, effective drugs in an FDA-approved manner.

### A. The Fact That A Manufacturer Could Avoid Conflicting Federal And State Requirements By Going Out Of Business Does Not Eliminate The Preemptive Effect Of Federal Law.

The state court's suggestion that petitioner could have avoided the inconsistent commands of federal

and state law by abandoning this line of business is at once correct and absurd. While complying with both federal and state law by going out of business is of course not physically impossible, the purpose and objective of Congress in permitting the sale of drugs under labels deemed proper by the FDA would clearly be frustrated if a state were free to drive a manufacturer out of business by setting up a conflicting regulatory scheme.

As Justice Garibaldi said in dissent, the FDA has the explicit mandate "'to act as *both* a public health *promoter* by facilitating the approval of important new safe and effective therapies, *and* as a public health *protector*, by keeping off or taking off the market drugs not shown to meet safety and efficacy standards.'" Pet. App 45a (quoting 50 Fed. Reg. 7,452 (1985)) (emphasis supplied by Justice Garibaldi). Justice Garibaldi noted that the effect of the state court's decision would be to bar the sale, on grounds of improper labeling, of a product that *federal* law deemed properly labeled. That is a clear subordination of federal labeling policy to state policy, in violation of the Supremacy Clause.

In virtually every conflict preemption case involving regulation of an industry, the regulated entity would avoid the conflict by going out of business. For example, in *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141 (1982), the regulated federal savings institution could have avoided the conflict between federal regulations permitting "due-on-sale" clauses and state law prohibiting them by not lending money at all or by "voluntarily" omitting the clause that subjected the institution to the conflicting commands of state and federal law. The Court neverthe-

less found that state law was preempted. Similarly, the television cable operator in *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 706 (1984), could have avoided the conflict between the FCC's "must-carry" rules, which prohibited deleting or altering any portion of the broadcast signals carried by the cable operator, and state criminal law, which prohibited commercials about certain alcoholic beverages, simply by going out of the cable business. As in *Fidelity Fed. Sav. & Loan*, this Court held that the state law "compels conduct that federal law forbids," and was therefore preempted. *Id.*

**B. The Fact That Federal Authorities Might Not Choose To Bring An Enforcement Action Does Not Eliminate The Preemptive Effect Of Federal Law.**

The state court next suggested that petitioner could have tried harder to persuade the FDA to allow the warning and if necessary could have run the risk of federal enforcement if (as here) petitioner were unsuccessful. The court did *not* deny that federal law appeared to require prior FDA approval of warnings, but instead said that federal law did not "clearly" do so, Pet. App. 32a. The court therefore suggested that petitioner could have taken the chance that the federal law would not be enforced against it. Pet. App. 33a.

The preemptive force of federal law is not eliminated by the fact that the state court found "no evidence indicating that the FDA ever took" enforcement action for similar violations of the labeling regulations. *Id.* There was no basis for a finding that the federal requirement had fallen into desuetude here. To require a federally regulated manufacturer to defy a federal pre-approval requirement in order to comply

with a conflicting requirement of state law and risk an enforcement action by the federal agency that has expressly denied giving approval plainly violates the Supremacy Clause.[7]

The state court's suggestion that petitioner should have "continued to press for FDA approval of a warning for Declomycin after the administration's initial response declining to change its official position," Pet. App. 39a, is equally unavailing. Petitioner had concededly followed all required federal procedures to obtain the FDA's approval of the warning that New Jersey now says petitioner should have used. Petitioner had provided the FDA with all the information petitioner possessed that would support the approval of the proposed warning. The FDA said no, on the basis of a complete factual record. There were repeated communications between petitioner and the FDA about warnings that should accompany Declomycin, despite which the FDA took the position, as late as July 1, 1963, that, because there was no evidence that Declomycin causes discoloration of teeth, there was no justification for a "change in our current formal position" denying the need for the warning. Pet. App. 10a. The state had no right to determine that *its* policy barred petitioner from taking "no" for

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[7] The existence of a conflict for purposes of the Supremacy Clause does not turn on how frequently an administrative agency may exercise its prosecutorial prerogatives. Indeed, a conflict could exist even if, for some inexplicable reason, Congress enacted a federal regulatory scheme without investing a federal agency with enforcement powers. Moreover, the presence or absence of enforcement actions by any particular group of federal officials does not guarantee that different enforcement priorities might not be adopted by their successors. Preemption doctrine cannot turn on such ephemeral considerations.

a *federal* answer after all *federal* procedures were properly followed.

There is no substance to the state court's notion that the alleged lack of "clarity" of the federal commands makes them any less "supreme." A requirement of "clear statement," as was imposed by the state court, is quite properly incorporated into *express* preemption analysis, where the question is whether Congress actually intended to bar application of state law. *See, e.g., Exxon Corp. v. Hunt*, 475 U.S. 355, 362-70 (1986) (express preemption cases require courts to analyze congressional purpose when language of statute is not clear). But where the question is whether the mandates of federal regulation conflict with state law, *conflict* preemption analysis requires no inquiry into congressional intent. *City of New York v. FCC*, 486 U.S. 57, 64 (1988) ("in a situation where state law is claimed to be pre-empted by federal regulation, a 'narrow focus on Congress' intent to supersede state law [is] misdirected,' for '[a] pre-emptive regulation's force does not depend on express congressional authorization to displace state law'") (quoting *Fidelity Fed. Sav. & Loan*, 458 U.S. at 154). *See also Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. at 142-43. In conflict preemption cases, the only question is whether the federal requirement as *properly* interpreted is inconsistent with the requirement that the state seeks to impose. The fact that the authorized federal agency could conceivably have interpreted the federal statute differently is wholly irrelevant. State courts are not free to avoid a conflict by deciding that a federal agency's interpretation of its governing statute is wrong.

**C. The Fact That Petitioner Could Comply With Federal Law But Pay State Tort Damages For Doing So Does Not Eliminate The Preemptive Force Of Federal Law.**

The state court also suggested (as did the petitioner in *Cipollone*) that petitioner could have complied with both federal and state policies by adhering to federal "prior approval" requirements while paying damages in tort suits for failing to provide the warning prohibited by federal law. Pet. App. 36a. In reaching this conclusion, the court adopted the reasoning of the federal appeals court in *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984), Pet. App. 32a, a decision that has been rejected explicitly by the Eleventh Circuit in *Papas*, *supra*, and implicitly by other federal appellate courts,[8] and one which in effect rewrites the Supremacy Clause.

The court in *Ferebee* held that there is nothing inconsistent in allowing states to require defendants to pay tort damages for violating state law (the duty to provide adequate warnings in that case), even where state law conflicts with federal law, because tort damages are intended to compensate plaintiffs, not to regulate conduct. *Ferebee*, 736 F.2d at 1541. A damages suit, according to the D.C. Circuit and now the New Jersey Supreme Court, does not actually require a defendant to alter its conduct; it only requires the defendant to pay money when compliance with federal law results in personal injury.

These decisions ignore reality; damage awards under state tort law are intended to and do in fact regulate conduct. It is well settled that damage

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[8] *See supra* footnote 6.

awards are designed, in part, to reflect and define duties imposed by law, such as the duty of care or (here) the duty to warn. *See Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 325-26 (1981) (state-court damages action for failure to provide adequate rail service would compel conduct otherwise regulated by federal agency); *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959) (allowing state damage award would regulate conduct left to the primary jurisdiction of National Labor Relations Board); *see also Cipollone v. Liggett Group, Inc.*, 789 F.2d 181, 187 (3d Cir. 1986) ("effect" of allowing state liability for failure to provide additional warnings would be to interfere with federal "balance of purposes"), *cert. denied*, 484 U.S. 976 (1987); *Baird v. General Motors Corp.*, 654 F. Supp. 28, 32 (N.D. Ohio 1986) (state tort liability for failure to install air bags in automobiles would "force automobile manufacturers to choose the air bag option over other statutorily approved options"); *cf. Shakil v. Lederle Lab.*, 561 A.2d 511, 529 (1989) (market share liability on vaccine manufacturers would discourage vaccine production). This Court stated clearly in *Garmon*:

> Our concern is with delimiting areas of conduct which must be free from state regulation if national policy is to be left unhampered. Such regulation can be as effectively exerted through an award of damages as through some form of preventive relief. *The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy.*

359 U.S. at 246-47 (emphasis added).

The payment of damages in a tort case occurs only when the defendant has violated a *duty* imposed by state law and the violation of that *duty* causes injury. The state law duty that was violated here, in the court's own words, was the "*duty* to warn of dangers of which [drug manufacturers] know or should have known on the basis of reasonably obtainable or available knowledge." Pet. App. 1a-2a (citing *Feldman v. Lederle Lab.*, 479 A.2d 374, 376 (N.J. 1984)) (emphasis supplied). But New Jersey is not free to impose that duty on petitioner because it is directly contrary to the duty imposed by federal law—*i.e.*, the duty to provide only those warnings that are authorized by the FDA and to refrain from using additional warnings disapproved by the agency. There can be no question that the two duties—the state duty to warn and the federal duty to provide only approved warnings—are in direct conflict. *Cf. Chicago & N.W. Transp. Co.*, 450 U.S. at 325-26 ("[i]t would vitiate . . . congressional intent . . . to permit the State of Iowa to use the threat of damages to require a carrier to do exactly what the Commission is empowered to excuse"); *Farmers Educ. & Coop. Union v. WDAY*, 360 U.S. 525, 531 (1959) (allowing respondent to maintain a slander suit "would sanction the unconscionable result of permitting civil . . . liability to be imposed for the very conduct the [federal] statute demands of the licensee"). When that is the case, the Supremacy Clause dictates that federal law shall prevail.

## CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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October 22, 1991

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91-685

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No. 91-

IN THE

# Supreme Court of the United States

OCTOBER TERM, 1991

LEDERLE LABORATORIES, Division Of American Cyanamid Company,

*Petitioner,*

v.

CAROL ANN FELDMAN,

*Respondent.*

## APPENDIX TO PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF NEW JERSEY

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**SUPREME COURT OF NEW JERSEY**
**A-93 September Term 1990**

CAROL ANN FELDMAN,
Plaintiff-Appellant,

v.

LEDERLE LABORATORIES, a Division of American Cyanamid Company, a Maine corporation doing business in the State of New Jersey,
Defendant-Respondent.

Argued January 14, 1991—Decided July 24, 1991

On certification to the Superior Court, Appellate Division, whose opinion is reported at 234 *N.J. Super.* 559 (1989).

*James I. Peck, IV*, argued the cause for appellant.

*William C. Slattery* argued the cause for respondent *(Morgan, Melhuish, Monaghan, Arvidson, Abrutyn & Lisowski* and *Norris, McLaughlin & Marcus*, attorneys; *Mr. Slattery* and *James L. Melhuish*, of counsel).

*Marc S. Klein* argued the cause for *amici curiae* pharmaceutical Manufacturers Association and E.R. Squibb & Sons, Inc. *(Sills, Cummis, Zuckerman, Radin, Tischman, Epstein & Gross*, attorneys).

*John L. McGoldrick* submitted a brief on behalf of *amicus curiae* Eli Lilly and Company *(McCarter & English*, attorneys).

The opinion of the Court was delivered by CLIFFORD, J.

In *Feldman v. Lederle Laboratories*, 97 *N.J.* 429 (1984) (*Feldman* I), we held that under the doctrine of strict products liability, "drug manufacturers have a duty to warn of dangers of which they know or should have known on

the basis of reasonably obtainable or available knowledge." *Id.* at 434. At the retrial following our remand, plaintiff argued that Declomycin, an antibiotic manufactured by defendant, Lederle Laboratories (Lederle), had permanently turned her teeth gray, and that the drug had been defective during the years 1960 to 1963 (the time she had used it) because it had lacked a warning that its ingestion by young children might result in tooth staining. Defendant attempted to show that relevant federal statutes and regulations had precluded it from performing its state-law duty to warn, and asserted that it could not be held liable for doing that which the federal law had compelled. The trial court rejected that argument and submitted to the jury plaintiff's strict-liability claim based on failure to warn. On the basis of its finding that Declomycin had not been defective in either 1960 or 1961 but that it had been defective in 1962 and 1963, the jury found in favor of plaintiff and awarded her $300,000.

The Appellate Division, concluding that "the theory of liability which undergirded the jury verdict against Lederle was preempted by federal law," 234 *N.J. Super.* 559, 564 (1989), reversed and remanded the case for entry of judgment in favor of defendant. We granted plaintiff's petition for certification, 122 *N.J.* 348 (1990), to determine whether her strict-liability cause of action based on failure to warn is preempted under the supremacy clause, *U.S. Const.* art. VI, cl. 2. We hold that in the circumstances of this case federal law does not preempt liability under state law. Consequently, we reverse the judgment of the Appellate Division and remand to that court for consideration of the other issues previously raised on appeal there but not decided. See 234 *N.J. Super.* at 564-65 n.3.

## I

### - A -

Tetracyclines, a group of antibiotics first introduced in 1948, are used to combat bacterial infections. A primary

benefit of tetracyclines is that they are effective against a wider variety of organisms than are other antibiotics. In 1959 Lederle introduced a new tetracycline analogue, demethylchlortetracycline, under the trade name Declomycin. The 1959 edition of the *Physicians' Desk Reference* (PDR), an annual used by doctors to determine the appropriate administration and effects of prescription drugs, stated that Declomycin had "greater antibiotic potency that made it possible to achieve therapeutic activity with less weight of antibiotic," that it had "a reduced renal clearance rate that produced a prolongation of the antibacterial levels in the body," and that it was "therapeutically equally effective as other tetracyclines in infections caused by organisms sensitive to the tetracyclines." *Feldman* I, *supra*, 97 *N.J.* at 436. The description did not mention tooth discoloration as a possible side effect. *Ibid.* Beginning some time after 1963, the *PDR* contained a warning that administration of Declomycin during the developmental stage of the permanent teeth—prenatal to approximately seven years of age—could cause permanent tooth discoloration. *Ibid.*

Plaintiff, Carol Ann Feldman, was born in 1960. Her father, Dr. Harold Feldman, testified that he had treated plaintiff with Declomycin two or three times a year between 1960 and 1963. He had not maintained records of the administrations but said that he had given the antibiotic only nine or ten times during that period. ("Times" refers not to individual administrations but to courses of treatment lasting an indeterminate but brief period.)

Shortly after Declomycin was introduced, Dr. Feldman became acquainted with it through a medical representative employed by Lederle. Dr. Feldman stated that the representative "informed me as to its qualities, to its effectiveness, to how it was being suggested in its use," and that the representative had left samples with the doctor after telling him "how useful the drug was in treating upper respiratory infections and how that was palatable

for children." The drug had been made available in cherry-flavored pediatric drops and syrup and custard-flavored oral suspension, and in varying forms of packaging, including clown-shaped bottles obviously intended for pediatric use. That no warning of the potential side effect of tooth discoloration accompanied the various forms of packaging of Declomycin prior to December 1963 is not disputed.

Plaintiff's baby teeth were discolored gray-brown. When plaintiff's permanent teeth began to erupt around 1965, Dr. Feldman became concerned because they too were discolored. After the family dentist examined plaintiff, he informed Dr. Feldman of "the possibility of a correlation between tetracycline and infant tooth staining." On learning from other physicians that some of them also were experiencing staining of teeth in patients treated with tetracyclines, Dr. Feldman stopped prescribing Declomycin for pediatric use.

No one disputes that the discoloration of plaintiff's teeth is the result of ingestion of tetracycline during the developmental stage of her permanent teeth, nor does defendant contest the jury's finding that Declomycin was the specific tetracycline involved. Rather, the dispute focuses on what action Lederle could and should have taken on acquiring knowledge of the correlation between the use of tetracyclines, particularly Declomycin, and staining of teeth.

Plaintiff contends that Lederle knew or through the exercise of reasonable diligence should have known of the possible serious and permanent side effects of Declomycin before and at the time she ingested the drug. She also asserts that Lederle "failed and refused to warn the plaintiff, pediatric consumers, and their physicians of those harmful effects in timely, adequate, and reasonable fashion." As evidence of Lederle's actual or constructive knowledge, plaintiff introduced at trial an internal Lederle

report dated August 28, 1962. The third page of the report, under the heading *"Declomycin-Achromycin,"* reads:

> We are beginning to hear comments about the yellowing discoloration of teeth in children following tetracycline therapy. One physician, already reported to [Lederle's corporate headquarters], also states his own children's second teeth are soft following tetracycline therapy. This physician states he will discontinue using tetracyclines until this phenomenon is proven or disproven.

Within three months of that report, Dr. Swanzey, an employee of Lederle from 1955 through the 1970s, wrote a letter to the Food and Drug Administration (FDA) notifying it of the possibility of a correlation between tooth discoloration and tetracycline use. In the letter, dated November 16, 1962, Lederle proposed adding the following warning to the labeling of all its tetracycline products: "Use of any tetracycline during tooth development in the neonatal period or early childhood may cause discoloration of the teeth." The letter continued: "Your early opinion and consideration is requested in order that this statement may be added at the earliest possible time."

Dr. Raymond Barzilai, a medical officer with the FDA, responded to Dr. Swansey's proposal by letter dated December 3, 1962. He indicated that the FDA had "not yet reached any form of final opinion (= medical, scientific, regulatory, etc.)," and was "currently devoting a great deal of active attention to the matter." Dr. Barzilai concluded: "[The FDA] will notify you as soon as any conclusion is reached." One copy of that letter bears a handwritten note suggesting that on its receipt, Lederle requested permission to disseminate the proposed warning in a circular but was "advised" by the FDA not to do so.

On January 15, 1963, Dr. Swanzey wrote to Dr. Barzilai with additional information relating to the possible cor-

relation of tetracycline use and tooth discoloration. He related that he had spoken with a Dr. Zegarelli, who

> confirmed that this phenomenon was peculiar to oxytetracycline, tetracycline, and chlortetracycline. He had no experience with demethylchlortetracycline. He felt that some statement is certainly indicated to be included in our package literature but expressed real concern that improper attention or publicity to this phenomenon should be avoided at all costs.
>
> We [Lederle] are conducting some further discussions with others who may have had experience with the use of tetracyclines during the various periods of tooth developments, and based upon this we will arrive at a statement concerning which I will discuss with you later.

By letter dated February 4, 1963, the FDA informed Lederle of the following:

> 1. After an extensive analytical review of the subject, this Administration has concluded that the effects on bone and teeth caused by the systemic use of the Tetracycline(s) products are clinically substantial and should be properly brought to the attention of the medical profession.
> 2. At present, the alleged teratogenic effects from tetracycline(s) have not been sufficiently documented as to justify any form of action within our authorized functions.
>
> The following warning statement is being proposed for insertion in the printed matter of all your Tetracycline products:
>
> "Tetracyclines may form a stable calcium complex in any bone forming tissue with no serious harmful effects reported thus far in humans. However, use of any tetracycline drug during tooth development (= last trimester of pregnancy, neonatal period and

> early childhood) may cause discoloration of the teeth (= yellow-grey-brownish). This effect occurs mostly during long-term use of the drug but it has also been observed in usual short treatment courses".
>
> * * * *
>
> In closing, I wish to mention that this Administration appreciated your initiative of offering constructive suggestions as well as your cooperative spirit.

On February 14, 1963, Dr. Swanzey agreed to incorporate the FDA's "suggested statement" in Lederle's literature and stated: "I assume that this statement is being proposed for chlortetracycline, oxytetracycline and demethylchlortetracycline as well." He continued:

> Before incorporating this in our labeling, however, I would like confirmation from you that it is acceptable to other manufacturers or if appropriate changes are to be made, thereby assuring that these effects *common to all of the tetracycline antibiotics* will be identical for all products.
>
> [Emphasis added.]

A letter of Dr. Barzilai dated February 18, 1963, furnished the requested confirmation:

> 1. This statement will have to appear only on the labeling for: Tetracycline, Chlortetracycline and Oxytetracycline. There is practically no specific clinical evidence to substantiate such a labeling requirement for Demethylchlortetracycline at present, but we intend to remain alert for such a future possibility.
>
> * * *
>
> 3. At any rate, I see no reasonable ground for any change in the wording of the statement and we [the

> FDA] expect to see it reproduced as is in the appropriate labelings as soon as possible.

In fact, the text of the warning was changed slightly, as Lederle learned from an FDA letter dated April 12, 1963. That letter went on to state: "We [the FDA] now have information that leads us to believe that this change in labeling should be made immediately. Therefore, we are asking that no further shipments be made of these drugs until the change has been made." Notably, although the letter displays a sense of urgency with respect to the warning, it, as well as other correspondence submitted by defendant, casts the FDA in a passive role. No change in the exception for Declomycin is indicated. That status was confirmed by a FDA press release issued April 18, 1963, which read in part: "'There is no evidence to date that a fourth drug, demethylchlortetracycline, causes the discoloration,' FDA said." In fact there was such evidence at that time, as indicated by subsequent correspondence, although that evidence may not then have been available to the FDA.

In response to the exchange with the FDA, Lederle issued a memorandum to all its salespeople on April 23, 1963. With respect to Declomycin, the memorandum stated:

> You will note that DECLOMYCIN is not included in the list of tetracycline analogues involved in this current revision. Therefore, the inserts and stickers are not to be attached to DECLOMYCIN circulars and literature. *While DECLOMYCIN has not been officially implicated with tooth staining it probably will be within a short period of time*, therefore, any gain by making an issue of this fact would rebound unfavorably at a later date. In the meantime, in answer to any questions from a doctor concerning DECLOMYCIN and tooth staining, your answer is, "DECLOMYCIN has not as yet been officially implicated with tooth staining."
>
> [Emphasis added.]

Significantly, that response by Lederle does not indicate any intention to prevent or curtail use of Declomycin by the at-risk group; nor does there appear to have been any consideration given to suspending production of Declomycin in the form of flavored pediatric drops, syrup, or oral suspension pending the probable implication of Declomycin with tooth staining. The answer to be given inquiring physicians can be described accurately as evasive.

Lederle continued to correspond with the FDA regarding the possibility of a correlation between Declomycin and tooth staining. That correspondence, however, did not attempt to convince the FDA that a warning for Declomycin was necessary. Rather, on May 8, 1963, Dr. Swanzey submitted additional information to the FDA with a letter stating: "This is our total experience to date and is certainly still insufficient to establish clearly that demethylchlortetracycline may cause tooth staining. It is probably premature to conclude that a warning in labeling is indicated."

Enclosed with that letter were publications and reports from practitioners strongly suggesting a correlation between Declomycin—as distinguished from tetracycline drugs in general—and tooth staining. The majority of those reports were in the possession of Lederle or its affiliates in 1962, with the most recent report being submitted to Cyanamid of Canada Limited (an affiliate of Lederle) in January 1963. The responsive letter from Cyanamid, dated February 1, 1963, stated in part: "At the present time and with the information available, it can only be postulated that the discoloration has indeed been the result of Declomycin administration, and one must admit that there appears to be a likely association."

On May 31, 1963, FDA Commissioner George Larrick wrote to Dr. Swanzey regarding the warning and labeling change for tetracycline drugs. With respect to Declomycin

he stated: "Actually, the original statement was revised to require the inclusion of the name of the drug in lieu of the word 'tetracyclines' because to date we have no evidence that your drug demethylchlortetracycline will stain teeth. If the warning statement as originally proposed is used, it automatically incriminates demethylchlortetracycline."

On July 1, 1963, Dr. Barzilai, responding to Lederle's letter of May 8th, stated:

> We have reviewed your information and we believe that it cannot as yet justify any change in our current formal position on this matter.
>
> You will realize, of course, that we need unequivocal factual evidence of adverse reaction in man to substantiate any official regulatory decision or action. Dr. Annett's case is only "suggestive" but, since grossly similar brown dental staining has long been observed in conditions other than Tetracycline treatment (cystic fibrosis is an example), this case would require further analysis by proper means (chemical, fluorescence, etc.) to eventually detect and identify the Tetracycline analogue.
>
> Your information will be filed in our records for future reference and be assured that we are following the development of this matter with utmost interest.

The record is silent on whether at any time Lederle undertook "further analysis by proper means" to confirm the suggested adverse reaction.

On November 11, 1963, Lederle's J. Kevin Rooney wrote to Dr. Barzilai that the manufacturer would incorporate a tooth-staining warning statement in all of its labeling for demethylchlortetracycline products. That letter was apparently a confirmation of a prior conversation authorizing the labeling change. The record does not reveal what additional information, if any, was brought to the FDA's

attention in order to justify the change in its "current formal position." Lederle submitted the revised labeling in December 1963 and incorporated it into the packaging of Declomycin shortly thereafter. The record contains no correspondence from the FDA reflecting its authorization of a change in labeling or its approval of the revised labeling submitted.

In 1975, Dr. Feldman wrote Lederle regarding the discoloration side effect. Lloyd S. Carr, then Lederle's Product Service Manager, replied in a letter stating that after "the causal relationship between tooth staining and tetracycline [had been] unquestionably demonstrated," Lederle had notified the FDA in November 1962 requesting permission to place a warning regarding discoloration on the labeling. Carr's letter went on to indicate that in April 1963 the FDA had "directed all manufacturers of tetracycline to include appropriate warnings in their labeling" but that Declomycin had been specifically excluded.

- B -

Plaintiff, through her father as *guardian ad litem*, filed suit in 1978 against Lederle and its parent corporation, American Cyanamid Company, seeking recovery under theories of negligence, gross negligence, breach of express and implied warranties, and strict products liability, among others. She alleged that Declomycin had been defective as marketed during the period when she had ingested the drug. A jury returned a verdict for defendant in 1980, and the Appellate Division affirmed in an unreported opinion. This Court granted plaintiff's petition for certification and summarily remanded the cause to the Appellate Division, 91 *N.J.* 266 (1982), for reconsideration in light of *Beshada v. Johns-Manville Products Corp.*, 90 *N.J.* 191 (1982). The Appellate Division again affirmed, 189 *N.J. Super.* 424 (1983), holding that *Beshada* did not apply and that prescription drugs are so important to society that suppliers should not be subject to strict liability. This Court

granted a second petition for certification, 94 *N.J.* 594 (1983), and reversed and remanded for a new trial, holding that prescription drug manufacturers are not immune from strict-liability claims. *Feldman* I, *supra*, 97 *N.J.* 429.

At the second trial in 1985 Lederle moved at the close of the evidence to dismiss the complaint on the basis of preemption. More specifically, it claimed that federal regulations in effect at the time of marketing and plaintiff's injury did not permit it to warn about the possibility of tooth staining without prior approval of the FDA. According to Lederle, compliance with the obligation under New Jersey law to communicate a warning based on subsequently-acquired actual or constructive knowledge of a danger "as soon as reasonably feasible," *Feldman* I, *supra*, 97 *N.J.* at 456, would have placed it in violation of federal regulations if the warning had been given without prior FDA approval. Lederle contended, therefore, that plaintiff's claim is preempted.

The court denied the motion, holding that the regulations at issue were not mandatory but discretionary, and

> [did] not in any way bar a drug manufacturer from, in accordance with the language of *Feldman* [I], putting out adequate warnings when information indicating that the product may be dangerous to the public comes to that drug manufacturer's attention.
>
> * * * *
>
> I am not satisfied that the defendant has in this record presented to the Court anything that would change the Opinion of the New Jersey Supreme Court in [*Feldman* I] to the effect that this area has been pre-empted by the Federal Government.

The court noted specially that Lederle had cited no administrative decisions or case law construing the regulation to be mandatory. Moreover, the court observed that Dr. Goddard, the commissioner of the FDA from 1966 to 1968,

had testified at a hearing pursuant to *Evidence Rule* 8 that the FDA had not been enforcing labeling regulations prior to his tenure as commissioner.

The jury returned a verdict for plaintiff on the sole count—alleging strict liability for failure to warn—of her amended complaint that the court had submitted. The verdict form reflected the following specific findings:

> 1. Plaintiff ingested Declomycin between 1960 and 1963.
>
> 2. There was not a defect in Declomycin because it failed to warn of tooth discoloration in 1960 and in 1961.
>
> 3. There was a defect in Declomycin because it failed to warn of tooth discoloration in 1962 and in 1963.
>
> 4. The failure to warn was a proximate cause of plaintiff's losses and injuries.

Lederle renewed its motion for judgment pursuant to *Rule* 4:40-2(b), and the trial court again denied the motion.

On appeal, Lederle continued to assert that plaintiff's claim based on failure to warn is preempted by federal laws and regulations governing labeling of antibiotics and prescription drugs. The Appellate Division reversed and remanded for entry of judgment in favor of Lederle:

> We conclude that the Food and Drug Administration's (FDA) regulation of the drug industry does not warrant a finding of implied federal preemption of all State tort claims grounded in strict liability failure to warn. However, under certain circumstances, such as presented here, federal law may preempt a discrete issue upon which liability is predicated because compliance with State decisional law would require federal law to be violated. Thus, plaintiff's entire cause of action was not preempted. However, the theory of liability not preempted was decided adversely to

> plaintiff by the jury and is not challenged on appeal, while the theory of liability which undergirded the jury verdict against Lederle was preempted by federal law. Thus, Lederle's motion for judgment notwithstanding the verdict should have been granted.
>
> [234 *N.J. Super.* at 564.]

From that ruling plaintiff petitioned for certification, which we granted. 122 *N.J.* 348 (1990). Plaintiff presents two distinct issues. First, she contends that the Appellate Division was bound by what she claims this Court decided in *Feldman* I, namely, that plaintiff's strict-liability claim based on failure to warn is not preempted by federal law. Second, plaintiff argues that even if the Appellate Division was free to consider the issue of preemption, its conclusion that plaintiff's claim is preempted by federal law was erroneous.

## II

The first issue is whether the Appellate Division was free to address the issue of preemption at all. Plaintiff contends that in *Feldman* I this Court determined that a cause of action based on failure to warn was not preempted by FDA regulations governing the labeling of prescription drugs. According to plaintiff, the Appellate Division was consequently precluded by the law-of-the-case doctrine from reconsidering the issue after remand.

The law-of-the-case doctrine is a guide for judicial economy based on the sound policy that "when an issue is once litigated and decided during the course of a * * * case, that decision should be the end of the matter." *State v. Hale*, 127 *N.J. Super.* 407, 410 (App. Div. 1974) (citing *United States v. United States Smelting, Ref. & Mining Co.*, 339 *U.S.* 186, 198, 94 *L.Ed.* 750, 760-61 (1950)). Plaintiff's argument, however, is more accurately consid-

ered as one of precedent and supremacy. If this Court had conclusively resolved the preemption issue in *Feldman* I, that determination would not have been open to re-examination by the lower courts on remand. *See Liptak v. Frank*, 206 *N.J. Super.* 336, 338-39 (App. Div. 1985), *certif. denied*, 103 *N.J.* 471 (1986); *In re Educ. Ass'n*, 117 *N.J. Super.* 255, 261 *certif. denied*, 60 *N.J.* 198 (1972). However, the precedential effect of an opinion depends on the court's intention to resolve an issue squarely presented. *See, e.g., Lehigh Valley R.R. v. Chapman*, 35 *N.J.* 177, 187, *cert. denied*, 368 *U.S.* 928, 7 *L.Ed.* 2d 192 (1961). Our analysis, therefore, necessarily turns to a determination of what we did—and did not—intend to resolve in *Feldman* I.

In *Feldman* I this Court noted that on the summary remand to the Appellate Division, defendant had raised for the first time the claim that federal regulations prohibited it from fulfilling its duty to warn because they precluded it from modifying its labeling without prior FDA approval. 97 *N.J.* at 458. The issue of federal preemption had been neither raised nor addressed at the first trial. *Ibid.* Consequently, Lederle had not presented evidence that FDA regulations had prevented it from warning as soon as it became aware of the necessity. *Id.* at 446-47. We stated: "Under these circumstances we would ordinarily defer discussion of the issue. However, since the trial court may be faced with the problem on the retrial, * * * *some comments are in order.*" *Id.* at 458 (emphasis added).

In contrast, we stated in a footnote to the antecedent paragraph, addressing the proper jury charge on the obligation to warn to be used at the retrial, that

> plaintiff did not object to the charge and did not raise this issue on her initial appeal. Since the cause must be retried, * * * and the issue was raised and argued before us, *we have decided the question.*

[*Id.* at 458 n.7 (emphasis added).]

The quoted and emphasized language establishes that this Court was not at a loss for precise expression when declaring the weight that should be accorded its pronouncements. The language of *Feldman* I taken in its entirety clearly indicates that it was not intended to resolve the preemption issue and therefore did not preclude defendant from making its preemption argument, with additional proofs, on remand. See *United States Smelting. Ref. & Mining Co., supra,* 339 *U.S.* at 198, 94 *L.Ed.* at 760-61.

III

The more substantial issue is whether the Appellate Division correctly decided that plaintiff's cause of action based on failure to warn is preempted because of actual conflict with the obligations imposed by federal laws and regulations in effect at the time of distribution and ingestion. We conclude that plaintiff's cause of action is not preempted, there being no direct conflict with federal law.

- A -

The preemption doctrine, rooted in the second clause of article VI of the United States Constitution, requires that when the mandates of federal law and state law are not consistent, the state law must yield. *See Wisconsin Pub. Intervenor v. Mortier,* ___ *U.S.* ___, 59 *U.S.L.W.* 4755, 4757 (1991). Federal regulations have the same preemptive effect as federal statutes. *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 *U.S.* 707, 713, 85 *L.Ed.* 2d 714, 721 (1985); *Capital Cities Cable, Inc., v. Crisp,* 467 *U.S.* 691, 699, 81 *L.Ed.* 2d 580, 589 (1984). Furthermore, the doctrine applies equally to state common law and state statutory law. *Chicago N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 *U.S.* 311, 325-26, 67 *L.Ed.* 2d 258, 270 (1981).

Preemption may occur in several ways. Provided Congress or the federal agency is acting within the scope of its authority, express language may exclude state law. *Schneidewind v. ANR Pipeline Co.*, 485 *U.S.* 293, 299, 99 *L.Ed.* 2d 316, 325 (1988). In the absence of a clear expression, the "intent to preempt all state law in a particular area may be inferred where the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress 'left no room' for supplementary state regulation." *Hillsborough County, supra*, 471 *U.S.* at 713, 85 *L.Ed.* 2d at 721 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 *U.S.* 218, 230, 91 *L.Ed.* 1447, 1459 (1947)). Where "the object sought to be obtained by federal law and the character of obligations imposed by it may reveal the same purpose," the intent to preempt state law will be inferred. *Rice supra*, 331 *U.S.* at 230, 91 *L.Ed.* at 1459. A third situation in which preemption will be implied occurs when "'the Act of Congress may touch a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.'" *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 *U.S.* 141, 153, 73 *L.Ed.* 2d 664, 675 (1982) (quoting *Rice, supra*, 331 *U.S.* at 230, 91 *L.Ed.* at 1459).

Conflict preemption occurs when "compliance with both federal and state regulations is a physical impossibility," *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 *U.S.* 132, 142-43, 10 *L.Ed.* 2d 248, 257 (1963), or when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 *U.S.* 52, 67, 85 *L.Ed.* 581, 587 (1941). Once the impossibility of dual compliance is established, the importance to the State of its own law is immaterial. *Felder v. Casey*, 487 *U.S.* 131, 138, 101 *L.Ed.* 2d 123, 138 (1988); *Brown v. Hotel Employees & Bartenders Int'l Union Local 54*, 468 *U.S.* 491, 503, 82 *L.Ed.* 2d 373, 384 (1984). When there is a conflict, "the federal law

must prevail." *Free v. Bland*, 369 *U.S.* 663, 666, 8 *L.Ed.* 2d 180, 183 (1962); *see also de la Cuesta, supra*, 458 *U.S.* at 153, 73 *L.Ed.* 2d at 675 ("state law is nullified to the extent that it actually conflicts with federal law"). The conflict, however, must be actual, not merely potential, speculative, or hypothetical. *Rice v. Norman Williams Co.*, 458 *U.S.* 654, 659, 73 *L.Ed.* 2d 1042, 1049 (1982).

In *de la Cuesta*, the Supreme Court addressed an alleged conflict between regulations issued by the Federal Home Loan Bank Board (Board) that authorized due-on-sale clauses (clauses that grant a lender the option to demand immediate payment of the loan balance if the subject property is sold or transferred without the lender's consent) in the loan contracts of federal savings and loan associations, and provisions of the California Civil Code that had been interpreted by the state to limit enforceability of such clauses. The Court found both a clear and manifest expression of an intent to preempt and an actual conflict:

> [California law] explicitly bars a federal savings and loan from exercising a due-on-sale clause to adjust a long-term mortgage's interest rate towards current market rates—a due-on-sale practice the Board has approved and views as critical to "financial stability of the association."
>
> [458 *U.S.* at 156, 73 *L.Ed.* 2d at 677.]

Because the Court also found that the Board was acting within its authority, the conflicting state regulations limiting due-on-sale practices of federal associations were preempted.

In contrast, in *Silkwood v. Kerr-McGee Corp.*, 464 *U.S.* 238, 78 *L.Ed.* 2d 443 (1984), the Court found that the Atomic Energy Act and its enacting regulations did not preclude an award of punitive damages under state law. The Court recognized that states had been expressly prohibited from regulating the safety aspects of hazardous

materials, but refused to extend that prohibition to state-law remedies for persons injured from radiation exposure in nuclear plants. *Id.* at 250-51, 78 *L.Ed.* 2d at 453-54. The Court rejected the contention that the award of damages would conflict with the federal remedial scheme, finding that "[p]aying both federal fines and state-imposed punitive damages for the same incident would not appear to be physically impossible." *Id.* at 257, 78 *L.Ed.* 2d at 458. It concluded that

> the provision cited by Kerr-McGee goes on to state that atomic energy should be developed and utilized only to the extent it is consistent "with the health and safety of the public." 42 *U.S.C.* § 2013(d). Congress therefore disclaimed any interest in promoting the development and utilization of atomic energy by means that fail to provide adequate remedies for those who are injured by exposure to hazardous nuclear materials.
>
> [*Ibid.*]

The Supreme Court has since unanimously confirmed that "'[o]rdinarily, state causes of action are not preempted solely because they impose liability over and above that authorized by federal law.'" *English v. General Elec. Co.*, ___ *U.S.* ___, ___, 110 *L.Ed.* 2d 65, 81 (1990) (quoting *California v. ARC Am. Corp.*, 490 *U.S.* 93, ___, 104 *L.Ed.* 2d 86, 97 (1989) (seven justices participating)). Furthermore, as stated in *English*, "[t]he 'teaching of this Court's decisions * * * enjoin[s] seeking out conflicts between state and federal regulation where none clearly exists.'" *Id.* at ___, 110 *L.Ed.* 2d at 81 (quoting *Huron Portland Cement Co. v. City of Detroit*, 362 *U.S.* 440, 446, 4 *L.Ed.* 2d 852, 858 (1960)).

Although "any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield," *Free, supra*, 369 *U.S.* at 666, 8 *L.Ed.* 2d at 183, the initiation point of the

preemption analysis depends on the area of law involved. Because plaintiff's claims concern rights and remedies traditionally defined solely by state law, namely, tort compensation, defendant here must overcome a presumption against preemption:

> When Congress legislates in a field traditionally occupied by the States, "we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."
>
> [*California v. ARC Am. Corp.*, *supra*, 490 *U.S.* at ___, 104 *L.Ed.* 2d at 94 (quoting *Rice v. Santa Fe Elevator Corp.*, *supra*, 331 *U.S.* at 230, 91 *L.Ed.* at 1459); *accord Mortier*, *supra*, ___ *U.S.* at ___, 59 *U.S.L.W.* at 4757 (adopting initial assumption stated in *Rice* "[w]hen considering pre-emption"); *see also Hillsborough County*, *supra*, 471 *U.S.* at 715, 85 *L.Ed.* 2d at 722 (recognizing a "presumption that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause").]

In *Silkwood*, the Court emphasized the absence of evidence that Congress had intended to preempt state-law claims or that it had even considered the issue. That absence of a clear and manifest purpose to preempt took on "added significance in light of Congress' failure to provide any federal remedy for persons injured by such [illegal] conduct." 464 *U.S.* at 251, 78 *L.Ed.* 2d at 454.

We recently considered preemption of a claim "traditionally defined solely by state law"—a strict-liability claim based on failure to warn—in *Dewey v. R.J. Reynolds Tobacco Co.*, 121 *N.J.* 69 (1990). In *Dewey* this Court rejected the argument that preemption was necessary because the incidental regulatory pressure exerted by a jury verdict would conflict with the Cigarette Act's secondary goal of uniform regulation. *Id.* at 88-94. Quoting *Silkwood*, we determined that such incidental regulatory effect does not

necessarily create a conflict sufficient to require preemption, even where direct state regulation is preempted expressly:

> "It may be that the award of damages based on the state law of negligence or strict liability is regulatory in the sense that a nuclear plant will be threatened with damages liability if it does not conform to state standards, but that regulatory consequence was something that Congress was quite willing to accept."
>
> [*Id.* at 89 (quoting *Silkwood, supra*, 464 *U.S.* at 256, 78 *L.Ed.* 2d at 457).]

Turning to an analysis of the actual regulatory effect that the imposition of state-law liability would have, this Court identified three options for the cigarette manufacturer: (1) "voluntarily" adding an additional warning, (2) adding an insert, and (3) "choosing to do nothing and risking exposure to liability." *Id.* at 90. Hence, the manufacturer would not be compelled to act in contradiction of the federal labeling requirement that expressly prohibits mandatory state labeling regulations. Furthermore, we stated that even if the manufacturer could not alter its label, a jury could conclude that the manufacturer nevertheless should bear the loss that could have been prevented with a more detailed warning label. *Id.* at 91-92; *see also Ferebee v. Chevron Chem. Co.*, 736 *F.*2d 1529, 1541 (D.C.Cir.) ("Even if Chevron could not alter the label, Maryland could decide that, as between a manufacturer and an injured party, the manufacturer ought to bear the cost of compensating for injuries that could have been prevented with a more detailed label than that approved by the EPA."), *cert. denied*, 469 *U.S.* 1062, 83 *L.Ed.* 2d 432 (1984). *But see Papas v. Upjohn Co.*, ___ *F.*2d ___ (11th Cir. 1991) (available on Westlaw, CTA11 database, 1991 WL 25740) (holding state tort actions for inadequate warning preempted by Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and its enacting regulations). This

Court noted in *Dewey* that FIFRA, the statute addressed in *Ferebee* and *Papas*, also contained a preemption clause presumably intended to promote uniformity of labeling, and agreed with the court in *Ferebee* that the existence of such a goal did not necessarily require a finding of preemption. 121 *N.J.* at 92; *cf. Burch v. Amsterdam Corp.*, 366 A.2d 1079, 1085 (D.C. 1976) (manufacturer of hazardous substance not immune from liability based on inadequate warning even though Federal Hazardous Substance Act precludes a state requirement unless such requirement is identical to the warning established by the Act); *MacDonald v. Ortho Pharmaceutical Corp.*, 394 *Mass.* 131, ___, 475 N.E.2d 65, 70-71 (compliance with FDA-approved labels does not immunize manufacturers from liability despite implied goal of precise and nationally-uniform labeling), *cert. denied*, 474 *U.S.* 920, 88 *L.Ed.* 2d 258 (1985).

Adopting here the reasoning of *Dewey*, we agree with the Appellate Division that plaintiff's claim is not preempted expressly or by implication. We diverge, however, from the Appellate Division's reasoning that that claim is barred because of a direct conflict between obligations imposed by federal law and those under state tort law. We did not reach that issue in *Dewey*. See 121 *N.J.* at 86. We also recognize that preemption in the regulation of prescription drugs raises somewhat different concerns from those related to regulating cigarettes that we addressed in *Dewey*. We therefore consider the reasoning of other jurisdictions that have addressed preemption in the context of FDA and similar regulations and focus our analysis on conflict preemption, specifically that body of case law addressing impossibility of dual compliance.

The Appellate Division adopted the reasoning of *Hurley v. Lederle Laboratories Division of American Cyanamid*, 851 *F.*2d 1536, *modified*, 863 *F.*2d 1173 (5th Cir. 1988), in concluding that plaintiff's warning claims were preempted due to conflict with obligations under federal law. See 234 *N.J. Super.* at 591-92. In *Hurley*, the plaintiff

alleged the failure to warn adequately of the possible severe adverse reactions to a vaccine and the production and marketing of an unreasonably-dangerous product. The district court granted partial summary judgment in favor of Lederle, finding that the Federal Food, Drug and Cosmetic Act of 1938 (FDCA), the Public Health Service Act (PHSA), and the regulations enacting them preempted *any* state-law claims based on defective design of the vaccine or on the inadequacy of its warning label. *Hurley, supra,* 851 *F.*2d at 1538.

Although the Fifth Circuit reversed and remanded, the court, in addressing conflict preemption, stated that the regulations at issue provide that the FDA determines a warning it deems appropriate and "[m]ost important[ly], the manufacturers cannot change the language * * * without FDA approval." *Id.* at 1542. The court then concluded that

> [i]t would be patently inconsistent for a state then to hold the manufacturer liable for including that precise warning when the manufacturer would otherwise be liable for *not* including it. Thus, assuming that the FDA has processed all the relevant and available information in arriving at the prescribed warning, its decision as to the proper wording must preempt by implication that of a state.
>
> [*Ibid.*]

The court limited the inquiry on remand to whether Lederle had withheld information from the FDA; "[o]therwise, the FDA-approved warning is sufficient." *id.* at 1543.

In *Abbot v. American Cyanamid Co.*, 844 *F.*2d 1108, *cert. denied*, 488 *U.S.* 908, 102 *L.Ed.* 2d 248 (1988), the Fourth Circuit was faced with the same issue presented in *Hurley*, namely, preemption of defective-design and failure-to-warn claims by FDA regulations governing vaccines. That court reversed the district court's finding of preemp-

tion, rejecting as its bases the comprehensiveness of the federal scheme and frustration of purpose. *Id.* at 1112-14. The Fourth Circuit also rejected the district court's determination that the warning given by the defendant was adequate as a matter of law despite acknowledging that the labeling "once approved, cannot be changed without FDA approval." *Id.* at 1112, 1115 ("adequacy of a warning is a question of fact for the jury").

In *Mazur v. Merck & Co.*, 742 *F. Supp.* 239 (E.D. Pa. 1990), the defendant asserted that the pervasive scheme regulating all aspects of vaccines compelled a finding of implied preemption. The court disagreed, despite finding that: (1) the regulation of vaccines is comprehensive; (2) the FDA had approved the package insert disseminated by the defendant and alleged to be inadequate; (3) the vaccine labeling must receive federal approval; and (4) the language of the labeling cannot be changed without authorization of the FDA. *Id.* at 244-46. Noting the strong presumption against preemption both of state tort remedies and in areas of health and safety, and recognizing that preemption would leave Pennsylvania citizens harmed by vaccines without a state tort remedy, that court agreed "with the great majority of courts addressing this issue that Congress did not impliedly preempt state regulation of vaccine manufacture, distribution, and labeling." *Id.* at 246 (footnote listing other cases in which no preemption was found omitted). *See generally* Annotation, *Federal Preemption of State Common-Law Products Liability Claims Pertaining to Drugs, Medical Devices, and Other Health-Related Items*, 98 *A.L.R. Fed.* 124 (1990) (collecting cases).

The court also rejected the defendant's narrower conflict preemption argument based on two observations equally appropriate to the circumstances here:

> [M]ere compliance with an FDA suggestion, or for that matter, regulation or order, does not mean that state tort law becomes irrelevant. First, compliance

with an FDA regulation may establish that the manufacturer met the appropriate minimum standards of due care, but compliance does not necessarily absolve the manufacturer of all liability. *See*, e.g., *Brochu v. Ortho Pharmaceutical Corp.*, 642 *F.*2d 652, 658 (1st Cir. 1981). Manufacturers must meet state safety requirements, whether codified or embodied in the common law, in addition to satisfying the initial FDA requirements.

Second, federal regulation serves a very different purpose [from] state tort law. Essentially, federal regulation serves a deterrent purpose by limiting the manufacture of inherently dangerous products to those applicants who meet certain stringent safety standards, while state tort law serves the equally important purpose of compensating individuals injured by those very same products. [*Because*] *compliance with FDA regulations will not ensure that a manufacturer's products will not cause injury, compliance will not necessarily exempt a manufacturer from liability. When those products do cause injuries. the state tort system provides a means of compensation.* State tort law is intended to supplement federal regulation by providing a vehicle for compensation of vaccine-related injuries.

[*Id.* at 247 (footnote omitted) (emphasis added).]

In *Ferebee v. Chevron Chemical Co.*, *supra*, 736 *F.*2d 1529, the issue was whether the extensive regulation of paraquat by the Environmental Protection Agency (EPA) and compliance therewith by a manufacturer precluded an inadequate-warning claim under Maryland law. Chevron contended that because the EPA, after careful consideration, had approved the labeling of the paraquat used by the plaintiff, the jury was bound by the EPA's determination and therefore could not find the labeling inadequate. *Id.* at 1540.

The court disagreed, reasoning that state tort law may have distinct and "broader compensatory goals." *Ibid.*

> [C]onceivably, a label may be inadequate under state law if that label, while sufficient under a cost-benefit standard, nonetheless fails to warn against any significant risk. In addition, even if the ultimate purposes of federal and state law in this area are the same, a state (acting through its jurors) may assign distinct weight to the elements which go into determining whether a substance as labelled is of sufficient net benefit as to warrant its use.
>
> * * * *
>
> [I]t need not be the case, as Chevron apparently assumes, that the company can be held liable for failure to warn only if the company could actually have altered its warning. * * * Maryland could decide that, as between a manufacturer and an injured party, the manufacturer ought to bear the cost of compensating for those injuries that could have been prevented with a more detailed label than that approved by the EPA. * * * Chevron can comply with both federal and state law by continuing to use the EPA-approved label and by simultaneously paying damages to successful tort plaintiffs such as Mr. Ferebee.
>
> [*Id.* at 1540-41.]

The Eleventh Circuit rejected the reasoning of *Ferebee* in *Papas v. Upjohn Co.*, *supra*, ___ *F.*2d ___, holding that "FIFRA impliedly preempts state common law tort suits against manufacturers of EPA-registered pesticides to the extent that such actions are based on claims of inadequate labeling." *Id.* at ___ (slip op. at 18) (footnote omitted). That court found preemption on several bases, including a direct conflict via a jury determination of inadequate warning with the EPA's determination that the labeling is adequate and with "the Congressional intent that *the*

*EPA Administrator* determine the reasonableness of the risks to man and the environment posed by pesticides." *Id.* at ___ (slip op. at 13). It also noted that the federal district courts are split on the issue. See *id.* at ___ n.1 (slip op. at 2-3) (collecting cases). The split among courts addressing the issue suggests that there is not a "clear and manifest" expression of congressional intent and calls into question the reasoning and authority of *Papas*.

Those cases finding preemption based on direct conflict typically have involved patently-incompatible affirmative obligations under federal and state laws. An example is *Grocery Manufacturers of America. Inc. v. Gerace*, 755 *F.*2d 993 (2d Cir.), *aff'd*, 474 *U.S.* 801, 88 *L.Ed.* 2d 29 (1985). In *Gerace* the plaintiff contended that New York regulations requiring use of "imitation" on labeling of cheese products directly conflicted with "imitation" as defined for use by federal regulations promulgated pursuant to the FDCA. Compliance with the state regulations would subject a manufacturer to liability for misbranding under federal regulations. The court agreed that compliance with both state and federal law was impossible and held the former to be preempted as applied to the specific area of "imitation" cheese. *Id.* at 1001.

In *Cosmetic, Toiletry & Fragrance Association v. Minnesota*, 440 *F. Supp.* 1216 (D. Minn. 1977), *aff'd*, 575 *F.*2d 1256 (8th Cir. 1978), the court was faced with federal and state labeling requirements for chlorofluorocarbons. The state statute and the FDA regulation required identical labels but differed on the location. *Id.* at 1219. Addressing the issue at the preliminary-injunction stage, the court found that the plaintiffs, who contended that the state regulations were invalid, had shown a substantial likelihood of success at trial on the preemption issue. *Id.* at 1225. It therefore issued the injunction. *Id.* at 1219.

We also note that in both *Gerace* and *Cosmetic, Toiletry & Fragrance Association* the purpose of the state enact-

ment was regulatory rather than compensatory. Here, the obligations under federal and state law are neither patently incompatible nor inconsistent regulatory efforts to accomplish the same purpose. See *English v. General Elec. Co.*, *supra*, ___*U.S.* at ___, 110 *L.Ed.* 2d at 81; *Silkwood*, *supra*, 464 *U.S.* at 263-64, 78 *L.Ed.* 2d at 462 (Blackmun, J., dissenting).

- B -

Turning our attention to this case, we begin by identifying the relevant state and federal laws operating in the field being considered. See *Chamber of Commerce of the United States v. State*, 89 *N.J.* 131, 142 (1982). Under New Jersey law a manufacturer is strictly liable for damages resulting from use of its products when the manufacturer fails to produce and distribute a product that is fit, suitable, and safe for its foreseeable purposes. *See Feldman* I, *supra*, 97 *N.J.* at 450. A product may be unsafe, and therefore defective, because of a failure to warn or an inadequate warning. *Freund v. Cellofilm Properties, Inc.*, 87 *N.J.* 229, 242 (1981). A manufacturer is obligated to communicate a warning based on subsequently-acquired knowledge of a danger "as soon as reasonably feasible." *Feldman* I, *supra*, 97 *N.J.* at 456. "Generally speaking, the doctrine of strict liability assumes that enterprises should be responsible for damages to consumers resulting from defective products regardless of fault." *Id.* at 450. When liability is premised on the failure to warn or an inadequate warning, the issue becomes whether the manufacturer knew or could have known of the danger and, if so, whether it "acted in a reasonably prudent manner in marketing the product or in providing the warnings given." *Id.* at 451-52. Under that standard negligence and strict liability in failure-to-warn cases may be deemed to be functional equivalents. *Id.* at 452.

The manufacture, sale, and marketing of prescription drugs is extensively regulated by the FDA pursuant to

the FDCA and its many amendments and enacting regulations. Specifically, section 331 of Title 21 of the United States Code prohibits the introduction into interstate commerce of any drug that is misbranded. A drug is deemed to be misbranded "[i]f its labeling is false or misleading in any particular," 21 *U.S.C.A.* § 352(a), if its labeling does not bear "adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health," *id.* § 352(f), or if it is an antibiotic drug, "unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 357 of this title, and (2) such certificate or release is in effect with respect to such drug." *Id.* § 352(l). For new drugs the federal scheme has a separate provision that "[n]o person shall introduce * * * into interstate commerce any new drug[] unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug." *Id.* § 355(a). The approval process includes review of the proposed labeling. The FDA will deny or withdraw approval if the "labeling is false or misleading in any particular" or "contains any untrue statement of material fact," or if "there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling." *Id.* § 355(d) and (e).

> As used in this subsection and subsection (e) of this section, the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed,

> recommended, or suggested in the labeling or proposed labeling thereof.
>
> [*Id.* § 355(d).]

Those statutory provisions are augmented by regulations for enforcement of the FDCA and for certification of antibiotic drugs. Lederle claims that the versions of those regulations in effect at the relevant time did not permit it, without prior approval of the FDA, to warn about the possibility of tooth staining. The pertinent regulations state in part:

> A supplemental application should be submitted for any change beyond the variations provided for in the application * * * that may alter the conditions of use, the labeling, the safety, identity, strength, quality or purity of the drug * * *. Labeling changes include deviations from the authorized brochure in any mailing or promotional piece used after the drug is placed on the market. When necessary for the safety of the drug, a supplemental application may be required to specify a period of time within which the proposed change will be made; and in such case the distribution of the drug after such time without such change constitutes distribution without an effective new-drug application. If a material change is made in the * * * labeling or advertising from the representations in an effective application for a new drug, and the drug is marketed before a supplement is effective for such change, the application may be suspended under § 130.27 on the grounds that it contains an untrue statement of a material fact.
>
> [21 *C.F.R.* § 130.9(a) (1960).]

Lederle also claims that warning without prior FDA approval would have violated regulations governing certification of batches of antibiotics, which stated:

> (b) A certificate shall cease to be effective:

* * * *

(2) With respect to any immediate container * * * when its label or labeling is altered, mutilated, destroyed, obliterated, or removed in whole or in part, or ceases to conform to any labeling requirement prescribed by the regulations in this part, except that:

(i) If the drug in such container is repacked * * *, and certification of the batch thus made is requested, such certificate shall continue to be effective for a reasonable time * * * ; [or]

* * * *

(iii) If its label or labeling is removed in whole or in part for the purpose of relabeling and supplemental certification of the relabeled drug is requested * * *.

[21 *C.F.R.* § 146.4 (1955).]

According to Lederle, compliance with the obligation under New Jersey law to communicate a warning based on subsequently acquired actual or constructive knowledge of a danger "as soon as reasonably feasible," *Feldman* I, *supra*, 97 *N.J.* at 456, would have placed it in violation of the federal statutes and regulations if the warning had been given without prior FDA approval. Relying heavily on subsequent amendments and statements regarding the labeling regulations and the FDA's interests with respect to drugs, the Appellate Division agreed, concluding that "the clear wording of [section 130.9(a)] required Lederle to seek the approval of the FDA to change the package inserts dispensed with the drug." 234 *N.J. Super.* at 588. The court felt constrained to conclude, based on the jury's findings on when Declomycin was defective, that the jury had found liability based on Lederle's failure to warn during the period it had corresponded with the FDA—November 1962 to December 1963. *Id.* at 573. The court then held

that principles of conflict preemption precluded the assessment of liability for failure to warn without prior approval during that period.

Implicit in the Appellate Division's conclusion is the notion that compliance with the letter of section 130.9(a) precludes finding for plaintiff on her strict-liability claim for failure to warn. Reading that provision in the context of the FDCA, however, and recognizing, as found by the Appellate Division, that "Congress' overriding purpose in enacting the FDCA was to protect consumers from dangerous drugs and antibiotics," *id.* at 581, we are satisfied that federal law did not clearly require that Lederle obtain prior approval from the FDA before warning of a known or knowable danger. Accordingly, we find nothing in the federal scheme to support the assertion that manufacturers of prescription drugs and antibiotics who literally comply with that isolated provision must be immune from state tort liability for injuries caused by their products. In the absence of a clear and manifest purpose to preclude the traditional workings of the tort compensation system, we find no conflict and hence no preemption.

We conclude that there is not a sufficient basis on which to find a direct conflict between state and federal law. The correspondence between Lederle and the FDA in 1962 and 1963 does not foreclose a finding either that state damage actions could act as compensatory supplements to the existing regulatory framework or that the FDA had neither considered nor addressed the preemptive effect of the regulations at that time. In light of the Supreme Court's concern, expressed most recently in *English* and *ARC America Corp.*, that injured plaintiffs not be denied a remedy in the absence of a clearly-expressed intention, we adopt the reasoning of *Abbot*, *Mazur*, and *Ferebee* here. Applying their reasoning will advance the primary purposes of both federal and state law, respectively, protecting the public health and compensating those injured when

that protection fails, without compelling drug manufacturers to violate federal statutes or regulations.

- C -

The FDCA "as a whole was designed primarily to protect consumers from dangerous products." *United States v. Sullivan*, 332 *U.S.* 689, 696, 92 *L.Ed.* 297, 303 (1948). We continue to believe, as we stated in *Feldman* I, that for the FDA to have prevented a drug manufacturer from warning the public of a newly-discovered danger pending development of unequivocal factual evidence of adverse reaction in man "would seem anomalous." 97 *N.J.* at 459. A direct conflict is not clear from the evidence presented—or attempted to be presented—at trial. Dr. Swanzey testified only to an industry understanding that the FDA regulations required prior approval. Dr. Goddard's report indicated that he believed the regulations required prior approval, but the relevant time period for this case was before his tenure as commissioner. Furthermore, his testimony at the *Evidence Rule* 8 hearing indicated that the labeling regulations had not been enforced before his arrival. The assertion that Lederle would have been subject to punishment for "misbranding" or would have had its product barred from the market if it had added an unapproved warning is based merely on Lederle's interpretation of the regulations then in effect. Lederle presents no evidence indicating that the FDA ever took such action for adding a warning suggesting a *limitation* on use rather than an unapproved representation of a benefit, nor does the record reflect any statement by the FDA to the effect that it would have taken action had a manufacturer attempted to warn without prior approval.

Lederle relies heavily on the modification of the new-drug labeling regulations in 1965 and subsequent statements of the FDA to support its argument that Congress and the FDA intended that modification of labeling without prior approval had not been allowed previously, namely,

at the time plaintiff had ingested the drug. The relevant FDCA-enforcement regulations were amended in 1965 to permit expressly "plac[ing] into effect at the earliest possible time" proposed additions to labeling "of additional warning, contraindication, side-effect, and precaution information." 30 *Fed. Reg.* 993 (1965) (codified at 21 *C.F.R.* § 130.9(d)). The amendment went on to add:

> It will be the policy of the Food and Drug Administration to take no action against a drug or applicant solely because changes of the kinds described in paragraph (d) of this section are placed in effect by the applicant prior to [its] receipt of a written notice of approval of the supplemental new drug application.
>
> [*Ibid.* (codified at 21 *C.F.R.* § 130.9(e)).]

The additions to section 130.9 were made effective immediately on publication in the Federal Register because they were in the interest of "drug safety" and "the public health, [were] noncontroversial, and relax[ed] existing requirements." *Ibid.* The regulations controlling antibiotics were similarly modified in 1966 to permit dissemination of modified labeling without awaiting advance approval. *See* 31 *Fed. Reg.* 11,415 (1966).

Although we recognize that subsequent actions of an agency are relevant to determining prior intent, *see Grove City College v. Bell*, 465 *U.S.* 555, 567, 79 *L.Ed.* 2d 516, 528 (1984), we do not agree that the conclusion that Lederle asserts necessarily follows. It contends that the modification shows that independent action was not permitted under the former regulations. An equally-compelling conclusion, however, is that the FDA had not addressed itself to the issue before. 3A Frumer & Friedman, *Products Liability* § 50.03(1), 50-255 n.37 (1990) ("One could argue that the changes made in § 130.9 in 1965 * * * indicate that FDA approval of precautionary information was required prior thereto. One could also argue that the change in language was meant to clear up a misconception.").

Arguably, then, on squarely considering the issue, the FDA determined that warning of possible dangerous side effects "at the earliest possible time," 30 *Fed. Reg.* 993 (1965), was consistent with its primary purpose to protect the public health.

There is additional support for that conclusion. The 1965 modifications did not materialize out of a vacuum. The changes were made to implement the Kefauver-Harris Drug Amendments enacted on October 10, 1962. See U.S. Food and Drug Administration, *Annual Reports 1950-1974* 374-75, 480-81, 527-28 (Dep't of Health, Education and Welfare 1976). The FDA understood those amendments to require that prescription-drug advertisements "contain a brief summary of information as to adverse side effects of the drug and warnings of when it should not be administered." *Id.* at 375. Dr. Goddard testified that the FDA regulations had not been enforced prior to his appointment as commissioner. That inaction could be explained rationally as recognition that the regulations in effect did not reflect the requirements of the FDCA as amended. The 1965 modifications to the regulations, then, demonstrate not an intent to require FDA pre-approval of warnings prior to 1965 but rather only an effort to clarify that in accordance with the purposes of the FDA, warnings of side effects were required. See 25 Fed. *Reg.* 12,595 (1960) (regulations governing labeling of new drugs were amended in 1960 for the express purpose of "requiring manufacturers to furnish adequate information for the professional use of prescription drugs and devices").

When the issue is viewed as which party should bear the loss occasioned by a product marketed without warning of its dangerous propensities, Lederle's contention based on the subsequent revision of the labeling regulations is even less persuasive. The 1965 modification and the pre-existing regulations are equally mute on the intention to deny compensation to persons injured by the use of antibiotic drugs. Lederle has not presented any evidence—

such as legislative history or an administrative decision—displaying a congressional intent to preempt all or any methods of tort compensation. The majority in *Silkwood* found no inconsistency in letting persons injured by nuclear hazards recover under state tort law despite Congress' express intent to have the Nuclear Regulatory Commission exclusively regulate the safety of nuclear facilities. 464 *U.S.* at 257-58, 78 *L.Ed.* 2d at 458. Notably, the dissenting justices agreed concerning the award of compensatory damages. See *id.* at 263-64, 78 *L.Ed.* 2d at 462 (Blackmun, J., dissenting) ("Because the Federal Government does not regulate the compensation of victims, and because it is inconceivable that Congress intended to leave victims with no remedy at all, the pre-emption analysis established by [*Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Commission*, 461 *U.S.* 190, 75 *L.Ed.* 2d 852 (1983),] comfortably accommodates—indeed it compels—the conclusion that compensatory damages are not preempted whereas punitive damages are" (footnote omitted).); *id.* at 275, 78 *L.Ed.* 2d at 469 (Powell, J., dissenting) ("Where injury is sustained as a result of the operation of a nuclear facility, it is not contested that *compensatory* damages under state law properly may be awarded."). We reach a similar conclusion here.

Finally, we note that a finding of preemption would leave plaintiff remediless, a fact that, based on *Silkwood* and *Dewey*, strengthens the presumption against preemption. See *Silkwood, supra*, 464 *U.S.* at 251, 78 *L.Ed.* 2d at 454; *Dewey, supra*, 121 *N.J.* at 84-85. However the action is viewed, the revision does not display a "clear and manifest" intent to preclude either (1) warning without prior FDA approval or (2) determining under state law that the manufacturer should bear the loss caused by a defective product, namely, a product marketed without a warning of a known or knowable dangerous side effect.

The Appellate Division, interpreting two cases from other jurisdictions addressing the regulations in effect at

the time of plaintiff's ingestion of Declomycin, found that both cases concluded that FDA approval was required prior to making a labeling change. 234 *N.J. Super.* at 588. One case, *Roginsky v. Richardson-Merrell, Inc.*, 378 *F.*2d 832 (2d Cir. 1967), assumed that advance permission from the FDA was required apparently because neither party had raised the issue. *Id.* at 835, 848. That court did not render a specific finding, nor did it indicate any authority compelling its conclusion. The other case merely cited *Roginsky*. See *Miller v. Upjohn Co.*, 465 *So.* 2d 42 (Ct. App.), *writ denied*, 467 *So.* 2d 533 (La. 1985). To the extent those cases addressed preemption of failure-to-warn claims, the analyses are uncompelling, and we decline to follow them.

The Appellate Division also strongly emphasized the FDA's interest in "rational prescribing." See 234 *N.J. Super.* at 593-95. However, the Commissioner of the FDA has stated that "[i]t is not the intent of the FDA to influence the civil tort liability of the manufacturer." 44 *Fed. Reg.* 37,437 (1979). In light of that unequivocal statement, we are unpersuaded that the asserted interest in rational prescribing precludes imposition of liability. Lederle's correspondence and internal documents establish that it knew or believed that there was an adverse causal association between Declomycin and tooth-staining. Lederle knew or believed that a portion of Declomycin users would be permanently injured by using the product as marketed. We are convinced that marketing Declomycin with that knowledge and belief constitutes the very conduct that the FDA intended not to absolve.

Finally, we note that Dr. Goddard testified that a manufacturer remained free to choose not to distribute a drug, an option cited in *Dewey* and *Ferebee* as additional support for a finding of no conflict. Lederle believed that a warning was necessary and proper for Declomycin. We find no basis to conclude that the FDA through its regulations mandated that Lederle disregard its determination and continue to

produce a drug that it believed to be unsafe as distributed. The testimony of Dr. Goddard persuasively suggests a contrary conclusion. Irrespective of what the regulations may have required with regard to changes in labeling, we find no basis for concluding that Lederle was required to continue marketing Declomycin in forms and packaging intended for use by those it believed to be at risk—or indeed to continue marketing at all. Such a requirement would conflict with the predominant, express purpose for which the FDA was created and for which the new drug regulations were enacted.

We also note that Lederle is not faced with the Hobson's choice of either complying with federal regulations and continuing to be subject to damages in state tort actions or providing additional warnings and thereby violating federal law. The regulations in question have long since been changed expressly to allow pharmaceutical companies to implement necessary changes in labeling while a supplemental new-drug application is pending. See 30 *Fed. Reg.* 993 (1965). Furthermore, the present regulations governing labeling of prescription drugs require that the labeling "describe serious adverse reactions and potential safety hazards, [and] limitations in use imposed by them." 21 *C.F.R.* § 201.57(e) (1990). Interestingly, that provision states that "labeling shall be revised to include [such] a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved." *Ibid.*

The issue then is what choices, if any, did Lederle have in 1962 and 1963. Even if we assume Lederle could not have provided a warning, an assumption we find unsupported by the evidence, it could have suspended production of Declomycin for what it termed the "probably * * * short period of time" before which Lederle anticipated that that drug too would be "officially implicated with tooth staining." Alternatively, Lederle could have quite reasonably and responsibly removed from the market those forms and

methods of packaging of Declomycin that were geared toward pediatric use. It could have raised the price as a form of loss-spreading insurance against claims. Lederle also could have continued to press for FDA approval of a warning for Declomycin after the administration's initial response declining to change its official position. (The record is conspicuously silent on any continuing efforts by Lederle to confirm the association of Declomycin with tooth staining or to gain FDA sanction of a warning for Declomycin. *Cf. Feldman* I, *supra*, 97 *N.J.* at 453 ("at least in some fields, such as those impacting on public health, a manufacturer may be expected to be informed and affirmatively to seek out information concerning the public's use of its own product").) The suggestion that Lederle was in some way compelled to continue distributing a drug without warning of the strong likelihood of serious side effects for some child users and that Congress and the FDA intended that it would be immune from liability for doing so cannot be reconciled with the primary purpose of the FDA to promote and protect the health of the citizens of the United States.

We find nothing in the record to justify a belief that Declomycin was different from the other tetracycline analogues in such a way that the discoloration side effect was unlikely to materialize. In fact, Lederle believed the evidence respecting Declomycin to be inevitably forthcoming "within a short period of time." The obvious reason for the lack of sufficient information on Declomycin was that Declomycin had been developed and introduced to the market later than the other members of the family of tetracyclines. The nature of the side effect precluded conclusive scientific information from being available until the permanent teeth of pediatric patients began to erupt. The issue, then, was not *whether* there would be evidence of tooth discoloration associated with Declomycin sufficient to justify the FDA in requiring a warning, but rather *when* such evidence would be available.

Simply stated, immunizing a drug manufacturer agains liability for marketing a product without a warning of known or knowable risk is in conflict with Congress' well recognized purpose in enacting the FDCA, particularly a amended in 1962. We will not recognize such an anomalou claim of immunity based solely on a manufacturer's rep resentations of the industry's belief. Here the evidence wa conclusive that tetracycline analogues were not safe fo children and that all other tetracyclines in existence long enough to provide data did not furnish adequate infor mation as labelled previously. The exclusion of Declomycir from the group approved for a label change was an un fortunate turn of events. We decline to visit the harm inflicted by a product on an innocent end-user by holding as a matter of law that Congress and the agency charged with protecting the public health intended to absolve from liability a manufacturer aware of the risk of that very harm.

We recognize that (assuming the price of Declomycin did not already include a "buffer factor" for unforeseen costs, an uncompelling assumption at best) Lederle might have had to increase the price of the product in order to absorb and spread the cost of the harm. So be it. Unlike the vaccines reviewed by the dissent, see *post* at ___ (slip op. at 21-25), Declomycin was not a wonder drug, without substitute or equipollent. The FDA "determination" in this case was really a non-decision—namely, that the evidence was not yet unequivocal or "substantial" as defined in the FDCA. It does not reflect a carefully-considered risk-benefit analysis of Declomycin's utility such that it should shield Lederle from plaintiff's claims for the harm caused by Declomycin. Lederle, believing that a warning would soon be required and that pediatric use of Declomycin would have harmful side effects, could not reasonably sit idly by, immunized from responsibility for those anticipated repercussions by legislation intended to promote the public

health. See *MacDonald v. Ortho Pharmaceutical Corp.*, *supra*, 394 *Mass.* 131, 475 N.E.2d 65.

IV

The record does not contain any formal administrative decision demanding deference from this Court. *See Young v. Community Nutrition Inst.*, 476 *U.S.* 974, 90 *L.Ed.* 2d 959 (1986). The subsequent amendments relied on so heavily by Lederle are susceptible of varying interpretations supporting both parties' positions. A finding of direct conflict is not compelled. This Court will not seek out a basis for such a finding. *See English v. General Elec. Co.*, *supra*, ___ *U.S.* at ___, 110 *L.Ed.* 2d at 81.

The presence of the following factors reinforces the traditional presumption against preemption: that there was no explicit provision for preemption of state tort claims; that the subject matter infringes on the State's inherent powers to protect and promote the health and safety of its citizens; and that preemption would effectively eliminate all means of recourse for the plaintiff. *See Dewey*, supra, 121 *N.J.* at 84-85; *Forster v. R.J. Reynolds Tobacco Co.*, 423 N.W.2d 691 (Ct. App. 1988), *aff'd in part and rev'd in part*, 437 N.W.2d 655 (Minn. 1989). If there had been a need to immunize prescription drug and antibiotic manufacturers from tort liability, the determination of that need should have been "made by Congress in an unambiguous mandate and *not* by the courts." *Forster*, *supra*, 423 N.W.2d at 701. To date Congress has not seen fit to express such a mandate. We will not do so in its stead.

V

As a final point in opposition to this appeal, Lederle raises the contention that "[i]f this case were again retried, there is no way that plaintiff could prevail." Lederle bases that contention on the hopeful conclusion that the rebuttable presumption created by *N.J.S.A.* 2A:58C-4 will be

conclusive on remand. We believe Lederle overstates the import of the statute.

Section four of the Products Liability Law, *N.J.S.A.* 2A:58C-4, creates a rebuttable presumption that a warning or instruction is adequate "if the warning or instruction given in connection with a drug * * * has been approved or prescribed by the federal Food and Drug Administration." The section also defines adequate warning as follows:

> An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, * * * in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician.
>
> [*Ibid.*]

Because the legislation affects the weight to be given FDA approval but does not change the burden of proof, it would apply to this cause on remand. *N.J.S.A.* 2A:58C-1 (section 8, not codified, provides for immediate effect); *see Shackil v. Lederle Laboratories*, 116 *N.J.* 155, 214 (1989) (O'Hern, J., dissenting).

The actual effect of the statute, however, is less clear. Its plain language defies the conclusion that the presumption cannot be overborne. Once the determination goes to the jurors, irrespective of an instruction from the court, they are free to disregard evidence of "approval" by the FDA. *Cf. McCormick on Evidence* § 344, at 978-79 (E. Cleary 3rd ed. 1984) (discussing instructions to jury when there is a presumption). Moreover, the statutory provision was enacted in the context of present FDCA, PHSA, and regulatory provisions that explicitly require warning of possible adverse side effects as soon as reasonably feasible

and based on "reasonable evidence." *See* 21 *C.F.R.* § 201.57(e) (1990). Consequently, under the unique circumstances of this case, compliance with the "determination" of the FDA not to require a warning for Declomycin due to the lack of "unequivocal factual evidence of adverse reaction in man," although evidence of the adequacy of the labeling, should not be accorded the same presumptive weight now given to warnings approved or prescribed by that agency, and certainly does not create a conclusive presumption that the labeling contained an adequate warning.

## VI

We hold that Lederle has failed to establish that civil tort liability is precluded because of an actual conflict with federal law and regulations. The case is remanded to the Appellate Division for consideration of those issues raised before that court but not addressed by it.

Chief Justice Wilentz and Justices Handler, Pollock, O'Hern, and Stein join in this opinion. Justice Garibaldi filed a separate dissenting opinion.

SUPREME COURT OF NEW JERSEY
**A-93 September Term 1990**

CAROL ANN FELDMAN,
Plaintiff-Appellant,

v.

LEDERLE LABORATORIES, a Division of American Cyanamid Company, a Maine corporation doing business in the State of New Jersey,
Defendant-Respondent.

GARIBALDI, J., dissenting.

The majority's narrow view of this case and the role of the Food and Drug Administration (FDA) prevent it from understanding the untoward implications its decision could have on the health of the many members of our society other than Carol Ann Feldman. The process that allows a prescription drug to be developed, tested, and marketed involves a complex balancing of the medical needs of everyone in our society against the risk that such drugs may present to any one person in that society. The majority's opinion upsets that balance.

Bad public policy emerges from the majority's intrusion into the field of prescription drug regulation. Its decision jeopardizes research and development of new drugs. It also will increase the cost of marketed drugs, thus escalating the nation's already spiraling health-care costs. Pharmaceutical manufacturers will be reluctant to develop and market drugs, in some instances, either withholding or withdrawing them from the market. People who need the drugs will be deprived of them because they are either not available or too expensive. Either way the public suffers. For those reasons, and because I am convinced that the majority introduces an unnecessary and unreasonable degree of confusion in this highly regulated area, I dissent.

I

Congress gave the FDA an explicit mandate "to act as *both* a public health *promoter* by facilitating the approval of important new safe and effective therapies, *and* as a public health *protector*, by keeping off or taking off the market drugs not shown to meet safety and efficacy standards." 50 *Fed. Reg.* 7452 (1985) (emphasis added). The FDA's mission is to ensure that each drug's "benefits outweigh its risks." *Id.* at 7469. The FDA must balance the "expected therapeutic gains" of each drug against the "risks entailed by its use." *United States v. Rutherford*, 442 *U.S.* 544, 555, 61 *L.Ed.* 2d 68, 79 (1979). The FDA cannot fulfill its role if state courts are allowed to require certain actions by pharmaceutical manufacturers that are prohibited under federal law and that supplant, rather than supplement, the carefully-considered regulations of a federal government agency. *See* Rose-Ackerman, *Tort Law in the Regulatory State*, in P. Schuck, *Tort Law and the Public Interest: Competition, Innovation and Consumer Welfare* 80, 100 (1991) (hereinafter Ackerman) ("Retaining conventional tort actions in the face of regulatory statutes can undermine the behavioral impact of [those] statutes.").

To enable the FDA to make those risk-utility determinations, Congress gave control to the FDA over virtually "every aspect of drug formulation, production, testing and labeling." Comment, *Federal Preemption of Prescription Drug Labeling*, 22 *J. Marshall L. Rev.*, 629, 656 (1989) (hereinafter Comment, *Federal Preemption*). The FDA promotes and protects health through a pervasive regulatory system that is exacting and time consuming. Even today "[p]harmaceutical product development is a long, tedious and expensive process . . . development time now averages twelve years." Comment, *Developing, Testing and Marketing An Aids Vaccine: Legal Concerns for Manufacturers*, 139 *U. Pa. L. Rev.* 1077, 1083 (1991) (Comment, *Legal Concerns for Manufacturers*).

In making its risk-utility analysis the FDA relies on a greater accumulation of information and expertise about the subject drug than can be found anywhere else. "The FDA has developed the highest level of competence in pharmaceutical investigation in the world." Comment, *Federal Preemption, supra,* 22 *J. Marshall L. Rev.* at 629. As was noted in 1967,

> [t]oday, side-effect data from numerous sources feeds into the FDA's Information Center on Adverse Reactions and Hazards, where it is studied and catalogued. Some 6600 hospitals supply the FDA with drug information. The agency also collaborates with the AMA central registry of adverse reactions, which receives drug news from hospitals not reporting to the FDA and from doctors in private practice. All federal medical services and agencies send side-effect reports to the FDA, and eight countries will exchange information through an international center created by the World Health Organization to provide a worldwide early warning system for new drugs.
>
> [Ruge, *Regulation of Prescription Drug Advertising: Medical Progress and Private Enterprise,* 32 *Law & Contemp. Probs.* 650, 659-60 (1967).]

*See also* 50 *Fed. Reg.* 7476-77 (1985) (calling for physicians to provide the FDA with direct information concerning suspected adverse reactions to drugs by means of form called Drug Experience Report (DER) or Form 1639). In addition to reaching out for such information, the FDA investigates and prosecutes violations and publishes "monthly reports on adverse reactions and a weekly journal of literature abstracts, which are sent to competing hospitals and other groups." Ruge, *supra,* 32 *Law & Contemp. Probs.* at 660.

"[B]ecause drug labeling is intended to advise health care professionals about potential hazards in the use of a

drug and convey documented statements about its safety," 44 *Fed. Reg.* 37,447 (1979), the FDA also makes a risk-utility determination about drug labeling. Because of its importance, drug "labeling" is expansively defined and extensively regulated by the FDA.

"Labeling" is defined to include "all labels or other written, printed, or graphic matter" on the container or "accompanying such article." 21 *U.S.C.A.* § 321(m). "[A]ccompanying such article" means any information that "supplements or explains" the labeling and "[n]o physical attachment one to the other is necessary." *Kordel v. United States*, 335 *U.S.* 345, 350, 93 *L.Ed.* 52, 57, *reh'gs. denied*, 335 *U.S.* 900, 93 *L.Ed.* 435 (1948), and 336 *U.S.* 911, 93 *L.Ed.* 1075 (1949). The "textual relationship" of the communication to the article is what is significant. *Ibid.* Thus, package inserts and all other communications to physicians with respect to the use or safety of the drug are considered to be "labeling" subject to FDA approval.

Even today, the FDA allows "labeling statements with respect to safety [only] if they are supported by scientific evidence," 44 *Fed. Reg.* 37,441 (1979). It demands that the "pharmacological information" in the label be "clinically relevant," *id.* at 37,442, and warn only of "known hazards and not theoretical possibilities." 21 *C.F.R.* § 201.57(d) (1991). The FDA has determined that a warning may not include a "statement of differences of opinion with respect to warnings (including contraindications, precautions, adverse reactions, and other information relating to *possible product hazards*) required in labeling food, drugs, devices, or cosmetics under this act," 21 *C.F.R.* § 1.21(c) (1991) (emphasis added). Simultaneously, following its "long-standing agency policy," the FDA demands that drug manufacturers continuously report to the FDA any unexpected or new side-effects, adverse reactions, or toxicity, "whether or not considered to be caused by the drug in question." 50 *Fed. Reg.* 7476 (1985). The FDA decision that a drug label is "an *authoritative document which con-*

*tains only those indications and usages which are based upon substantial evidence,*" 40 *Fed. Reg.*15,394 (1975) (emphasis added), reflects a conscious policy choice that certain information it gathers not be included in drug labeling.

Despite their portrayal by the majority, today's prescription drug manufacturers enjoy only a "very limited freedom," a freedom not enjoyed at all before 1965, to make temporary, conditional labeling changes. Note, *Federal Preemption: A Vaccine Manufacturer's Defense*, 56 *U. Mo.-K.C. L. Rev.* 515, 529 (1988) (hereinafter Note, *A Vaccine Manufacturer's Defense*). Even that freedom evaporates once the FDA has ruled. *See ibid.* The FDA must enforce its best assessment of the proper risk-benefit balance because of the unique concerns associated with pharmaceuticals.

Prescription drugs are unlike typical consumer goods, on which stringent warnings of possible dangers have no appreciable negative impact on the utility and use of the product and should rarely be omitted. *See, e.g., Freund v. Cellofilm Properties, Inc.*, 87 *N.J.* 229, 242 (1981). Pharmaceuticals also differ from some other products, such as cigarettes, in respect of which a negative impact on "utility" or use is not only a tolerated byproduct of a warning but often a targeted goal. *See, e.g., Dewey v. R.J. Reynolds Tobacco Co.*, 121 *N.J.* 69, 100 (1990) (noting legislative attempts to discourage smoking); *see also* Recent Development, *Tort Law—Strict Products Liability—New Jersey Supreme Court Preserves Claims Against Tobacco Companies—Dewey v. R. J. Reynolds Co.*, 121 *N.J.* 69, 577 A.2d 1239 (1990), 104 *Harv. L. Rev.* 1723, 1727 (1991) ("A second defense of strict liability * * * argues that forcing the industry to internalize the health costs of smoking will raise cigarette prices and thus encourage smokers to cut back or quit.") Despite those differences the majority's analysis proceeds uninfluenced by the conflicting policy considerations this case presents.

The uses and benefits of prescription drugs like Declomycin, and the analysis of those uses and benefits, differ markedly from an appraisal of the social benefits of paint mixers or cigarettes. *See Brown v. Superior Court*, 44 *Cal.* 3d 1049, 1063, 751 P.2d 470, 478-79, 245 *Cal. Rptr.* 412, 420 (1988) (decision in any given pharmaceutical case must recognize and reflect broad policy considerations occasioned by "important distinction between prescription drug and other products"). Warning of the possible but not scientifically-verifiable side-effects of prescription drugs can have a significant anti-utilitarian effect, especially if required only in certain states. *Cf. ibid.* ("broader public interest in availability of drugs at affordable prices must be considered in deciding appropriate standards of liability for injuries resulting from their use" because beneficial drugs are necessary despite fact that "harm to some users is unavoidable"). As the FDA has said, "[t]o permit or require statements of conflicting opinion on all these matters would destroy the present usefulness of prescription drug labeling." 39 *Fed. Reg.* 33, 232 (1974). It would also destroy the FDA's hope of " 'bringing consistency and uniformity to the marketplace' " or of succeeding in its " 'well-established policy of promoting uniformity in the area.' " *See* Comment, *Legal Concerns for Manufacturers*, *supra*, 139 *U. Pa. L. Rev.* at 117 n.190 (quoting 51 *Fed. Reg.* 8181 (1986), and 50 *Fed. Reg.* 51,403 (1985), respectively).

The FDA has expressed two serious concerns about drug labeling. First, it has an interest in "rational prescribing," *i.e.*, ensuring that the risks and benefits of a particular drug be fairly presented so that a physician can compare them with other available therapies. That goal is not advanced if a drug is made to appear riskier than other drugs and other therapies due to the over-dramatization of risk information. To allow a warning based on inconclusive evidence or scientific hunches results in doctors not

prescribing effective drugs to a patient because of the erroneous belief that a side-effect might occur.

In addition to promoting "rational prescribing," the FDA must prevent "information overload." As one court has noted:

> The quality of evidence supporting a causal connection between product and injury may change from extremely vague to highly certain. * * * [I]f every report of a possible risk, no matter how speculative, conjectured, or tentative, imposed an affirmative duty to give some warning, a manufacturer would be required to inundate physicians indiscriminately with notice of any and every hint of danger, thereby inevitably diluting the force of any specific warning given.
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> [*Finn v. G.D. Searle & Co.*, 35 *Cal.* 3d 691, 701, 677 P.2d 1147, 1153, 200 *Cal. Rptr.* 870, 876 (1984).]

The FDA has legitimate concerns that information overload may lead physicians to ignore drug labels or package inserts or to read them without any intention of modifying their prescription practices because substantial parts of what they have found in them in the past had not been useful or had later been disproved. See Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 *Harv. L. Rev.* 773, 783 (1990) (hereinafter Note, *Pharmaceutical Regulation*).

The FDA has an interest in promoting health. Ensuring that drug scares do not occur and that unsubstantiated claims, good or bad, do not appear on the label is a way of achieving that goal. Even today, under 21 *C.F.R.* § 310.303(a) (1991), the FDA receives information regarding every possible side-effect, but issues warnings based only on reasonable evidence, because "statements of conflicting opinion * * * would destroy the present usefulness

of prescription drug labeling." 39 *Fed. Reg.* 33,232 (1974). That policy balance represents the expert appraisal of how best to maximize aggregate health benefits. The dual function of the FDA ensures that drug companies produce and market medications that "decrease aggregate health risks as safely and inexpensively as possible," Note, *Pharmaceutical Regulation*, *supra*, 103 *Harv. L. Rev.* at 780, because "Americans insist on the best available medications to treat those suffering from illness." Comment, *Federal Preemption*, *supra*, 22 *J. Marshall L. Rev.* at 629.

Against that background, we review this case.

II

-A-

I agree with the Appellate Division. Although the comprehensive nature of FDA regulations and the national goal of uniformity in drug labels tempts me to find implied preemption, I need not reach that issue here. The Appellate Division's narrower holding disposes of this case and addresses those concerns that force me to disagree with my colleagues:

> We conclude that the Food and Drug Administration's (FDA) regulation of the drug industry does not warrant a finding of implied federal preemption of all State tort claims grounded in strict liability failure to warn. However, under certain circumstances, such as presented here, federal law may preempt a discrete issue upon which liability is predicated because compliance with State decisional law would require federal law to be violated.
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> [234 *N.J. Super.* at 564.]

"[E]ven in the absence of express language on implied congressional intent to occupy the field, state law may be preempted 'to the extent that it actually conflicts with

federal.'" *Dewey, supra*, 121 *N.J.* at 78 (quoting *Brown v. Hotel Employees Int'l Union*, 468 *U.S.* 491, 510, 82 *L.Ed.* 2d 373, 383 (1984)). Federal regulations have the same preemptive effect as federal statutes, *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 *U.S.* 707, 713, 85 *L.Ed.* 2d 714, 721 (1984), and state common law and state statutory law stand equally subject to preemption. *Chicago N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 *U.S.* 311, 325-26, 67 *L.Ed.* 2d 258, 270 (1981).

I agree with the Appellate Division that the "clear wording" of the regulations in place before 1965 prevented the defendant, Lederle Laboratories, from complying with the common-law duty this Court now imposes on it. 234 *N.J. Super.* at 588; *see Roginsky v. Richardson-Merrell, Inc.*, 378 F.2d 832, 835, 848 (2d Cir. 1967) (interpreting pre-1965 regulations to require prior FDA approval before a labeling change could be made); *Miller v. Upjohn Co.*, 465 *So.* 2d 42, 45 (La. Ct. App. 1985) (same), *cert. denied*, 467 *So.* 2d 533 (1985) (same); *see also Hurley v. Lederle Laboratories*, 863 F. 2d 1173, 1179, *modifying* 851 F. 2d 1536, 1542 (5th Cir. 1988) (because it is "[m]ost important [that] the manufacturers cannot change the language in the product insert without FDA approval," court found that direct conflict preempted adequacy of warning issue as long as Lederle had met its duty to disclose all relevant information to FDA).

The plain wording of the two regulations relevant here support that position. The first, 21 *C.F.R.* § 130.9(a) (1960), states in part:

> A supplemental application should be submitted for any change beyond the variations provided for in the application * * * that may alter the conditions of use, the labeling, the safety, identity, strength, quality or purity of the drug * * *. Labeling changes include deviations from the authorized brochure in any mailing or promotional piece used after the drug is placed

> on the market. When necessary for the safety of the drug, a supplemental application may be required to specify a period of time within which the proposed change will be made; and in such case the distribution of the drug after such time without such change constitutes distribution without an effective new-drug application. If a material change is made in the * * * labeling or advertising[] from the representations in an effective application for a new drug, and the drug is marketed before a supplement is effective for such change, the application may be suspended under § 130.27 on the grounds that it contains an untrue statement of a material fact.

The other regulation of primary relevance, which defined the FDA's position on the certification of batches of antibiotics, stated:

> (b) A certificate shall cease to be effective:
>
> * * * *
>
> (2) With respect to any immediate container * * * when its label or labeling is altered, mutilated, destroyed, obliterated, or removed in whole or in part, or ceases to conform to any labeling requirement prescribed by the regulations in this part, except that:
>
> (i) If the drug in such container is repacked * * *, and certification of the batch thus made is requested, such certificate shall continue to be effective for a reasonable time * * * ; [or]
>
> * * * *
>
> (iii) If its label or labeling is removed in whole or in part for the purpose of relabeling and supplemental certification of the relabeled drug is requested, as provided by § 146.18.
>
> [21 *C.F.*R. § 146.4 (1955).]

Each of those regulations clearly indicates the need to obtain approval before altering labels. *See* L. Tribe, *American Constitutional Law* § 6-26 at 482 (1988) (Implication can still amount to direct preemption because "state and federal law need not be contradictory on their face for the latter to supersede the former. There are more subtle forms of actual conflict.").

Subsequent history also discloses that Lederle could not alter its label without approval under the FDA regulations governing changes in drug labeling in effect during 1962 and 1963. In January 1965, the FDA amended the form of the New Drug Application prescribed in 21 *C.F.R.* § 130.4 (1956), and the requirement of filing a supplemental application set forth in 21 *C.F.R.* § 130.9 (1960), to allow a manufacturer to incorporate additional warnings of side-effects in its labeling prior to receiving a written notice of approval of the supplemental new drug application from the FDA. See 30 *Fed. Reg.* 993 (1965). In *Feldman v. Lederle Laboratories*, 97 *N.J.* 429 (1984) (*Feldman* I) we mistakenly suggested, on an incomplete record, that those amendments might have merely clarified existing procedures. *Id.* at 459. We know now that that is not so. The former Commissioner of the FDA explained that the regulations were "amended * * * *to enable* prompt adoption" of changes," and that the amendments were intended to "*relax* existing requirements." 30 *Fed. Reg.* 993-94 (1965) (emphasis added).

History is particularly telling in the case of antibiotics. Although Congress immediately recognized that antibiotics "are spectacularly efficacious in many serious diseases suffered by large numbers of our population," it was very concerned about the complicated manufacture and safe use of antibiotics. *Hearings Before a Subcommittee of the House Committee on Interstate and Foreign Commerce*, 81st Cong., 1st Sess. 5 (1940). Accordingly, Congress imposed on antibiotics "even more stringent regulations" than those generally imposed on prescription drugs. *See Pfizer, Inc.*

*v. Richardson*, 434 F.2d 536, 538 (2d Cir. 1970). After the initial approval of an antibiotic, but not other drugs, the manufacturer was required to request certification of each batch before it was marketed. *See* 21 *C.F.R.* §§ 146.2 & 146.3 (1963). Thus, before a batch of antibiotic could be certified, the FDA was required to find affirmatively that the labeling did not contain any "untrue statement of a material fact," that it contained "all words, statements, and other information required by the regulations," and that it otherwise met all the statutory standards for *adequate* warnings. *See* 21 *C.F.R.* §§ 146.3 & 146.4 (1963).

Moreover, the FDA precluded drug manufacturers from altering approved labeling in any respect without prior authorization. The certification of any batch of antibiotics was immediately void if the "labeling [had been] altered * * * in whole or in part, or [had ceased] to conform to any labeling requirement." 21 *C.F.R.* § 146.4(b) (2) (1963). Even the 1965 amendments did not change the batch certification requirements applicable to antibiotics. Only in 1966 did the FDA modify its antibiotic regulations to allow manufacturers to use "mailing and promotional pieces that are essentially the same as the previously approved labeling" without "advance approval" from the agency. 31 *Fed. Reg.* 11,415 (1966). In explaining that change, the then-Commissioner of FDA stated that "heretofore, the regulations have *required specific advance approval* of each mailing piece." *Ibid.* (emphasis added). Except for that minor change, however, the FDA approval procedures for changes in antibiotic labeling remained intact.

The FDA's intent to prevent pharmaceutical manufacturers from changing drug labels without the FDA's approval is confirmed by the regulations. *See Grove City College v. Bell*, 465 *U.S.* 555, 567, 79 *L.Ed.* 2d 516, 528 (1984). The 1965 amendments "relaxe[d]" existing standards and "enable[d]" manufacturers to take previously-prohibited actions. *See* 30 *Fed. Reg.* 993-94 (1965). Neither did the FDA then, nor does it now, believe "warning of

*possible* dangerous side effects * * * [to be] consistent with its primary purpose." *Ante* at ___ (slip op. at 41-42) (emphasis added). Labels should warn only of "*known* hazards and *not theoretical possibilities*," 21 *C.F.R.* § 201.57(d) (1991) (emphasis added), and these "warnings" should describe only those "adverse reactions" and "safety hazards" that have a demonstrated "association" with the subject drug. 21 *C.F.R.* § 201.57(e) (1991).

-B-

The facts also support the position that if Lederle had placed on its label for Declomycin the additional warning now required by the majority, it would have been in direct conflict with the FDA's strict drug-labeling regulations.

I agree with much of the majority's discussion of the facts, including the observation that the ingestion of Declomycin during the developmental stages of plaintiff's teeth caused the injury alleged here. However, I highlight those facts that are most salient to the present inquiry.

Tetracyclines, a generic label for a group of antibiotics, of which Declomycin is one,[1] marked a great advance in the fight against bacterial infections. *See United States v. An Article of Drug*, 394 *U.S.* 784, 785, 22 *L.Ed.* 2d 726, 729 (1969) (describing tetracyclines as "wonder drugs"). "A primary benefit of tetracyclines is that they are effective against a wider variety of organisms than are other antibiotics." *Ante* at ___ (slip op. at 3).

> Declomycin "had greater antibiotic potency that made it possible to achieve therapeutic activity with less weight of antibiotic," * * * it had "a reduced renal clearance rate that produced a prolongation of the antibacterial level in the body," and * * * it was "therapeutically equally effective as other tetracy-

[1] Declomycin is the trade name used by Lederle for demethylchlortetracycline, a tetracycline analogue.

> clines in infections caused by organisms sensitive to the tetracyclines."
>
> [*Ibid.* (quoting *Feldman* I, *supra*, 97 *N.J.* at 436.]

Those proven qualities made Declomycin a beneficial addition to medical-treatment programs throughout this country when it was introduced in 1959.

In 1962, defendant began to receive anecdotal reports regarding a possible link between the use of tetracycline by children during their developmental years and the subsequent yellowing of some users' teeth. Lederle quickly notified the FDA of the possible link and proposed a warning label. The FDA responded that it had been "devoting a great deal of attention to the matter" over "the past several months" Letter from FDA to Lederle (Dec. 3, 1962). The FDA had received reports "of this type from here and abroad," and, although it was "acutely interested" in the problem and was "fully aware of the importance of the various implications of this problem," it did not order Lederle to augment or alter its current label. *Ibid.*

Defendant continued to supply information to the FDA during the agency's research on Declomycin. In early 1963, the FDA directed that a warning label be placed on certain tetracycline analogues to alert users to a demonstrated link between these drugs and tooth staining. The FDA had removed the generic label "tetracycline" from its proposed warning and specifically excluded Declomycin because there was "practically no specific clinical evidence to substantiate such a labeling requirement." Thus, the FDA refused to approve immediately Lederle's desired warning for Declomycin's labeling, and it further forced Lederle to exclude its originally-approved blanket statement from declomycin labeling because there was insufficient information to "substantiate" the clinical association necessary to support such a labeling requirement.

On April 18, 1963, the FDA issued the following press release to all medical and dental journals, and to the general media, with respect to tooth discoloration and tetracyclines. That release, in pertinent part, said:

> "Children's teeth can be seriously discolored by three types of tetracycline antibiotics," the Food & Drug Administration said in a message to physicians and dentists.
>
> "The three drugs are: tetracycline, chlortetracycline, and oxytetracycline. *There is no evidence that a fourth drug, [Declomycin] causes the discoloration," FDA said.*
>
> [Emphasis added.]

Thus, if Lederle had issued the warning required by the majority, it would not only have proceeded without the FDA's approval of its desired warning, it also would have directly contradicted the public position of the FDA. *Cf.* L. Tribe, *supra*, § 6-26 at 483 (state law will be preempted "if its effect is to discourage conduct that federal action specifically seeks to encourage").

Accordingly, this record unambiguously demonstrates a direct conflict. The majority need not search it out. It emerges clearly from the totality of the evidence in this record.

-C-

The majority's opinion's assumptions and inferences have no basis in the record. The majority unfairly casts Lederle as a scheming dissembler that provided evasive answers and caused some sort of knowing delay in FDA decisions by suppressing information. Were that true, my position here might be different. *Cf. Silkwood v. Kerr-McGee Corp.*, 464 *U.S.* 238, 257, 78 *L.Ed.* 2d 443, 458 (1984) (when "federal standards have been violated," paying both fed-

eral administrative fines and state tort damages does not "frustrate any purpose" of a pervasive federal scheme). I would not countenance a result that insulated a manufacturer who violated federal standards by delaying or disrupting, through action or inaction, the flow of information to the FDA, by refusing to investigate independently the possibility that its drugs were harmful, or by using administrative delay as an opportunity to unload on the public drugs known to be unsafe. *See Hurley, supra*, 863 F.2d at 1179-80.

However, nothing like that occurred here. Lederle violated no federal standards—indeed, Lederle went so far beyond mere adherence that it drew praise from the FDA. Although Lederle certainly had information implicating a potential connection between tooth staining and tetracyclines, no one, including the FDA, "could * * * come to any conclusions as to what exactly was going on," according to one witness. Another witness noted that Declomycin, unlike two other tetracycline analogues, had not been demonstrably linked to tooth discoloration by 1963. Another witness stated that Declomycin had "initially [been] thought to have even less effect on tooth staining than the original tetracyclines." Moreover, Lederle warned its sales staff not to use the FDA's exemption of Declomycin from its order for revised warnings to gain market advantage. I see no evasion in the answer "Declomycin has not *as yet* been *officially* implicated in tooth staining." (Lederle memorandum dated April 23, 1963) (emphasis added). Indeed, the modifying language "as yet" and "officially" indicates even to the most unsophisticated physician that that status might change. Despite that evidence, the majority makes the unsupported assumption that evidence that would have demonstrated a known hazard and not a theoretical possibility would "not then have been available to the FDA," *ante* at ___ (slip op. at 9), yet existed for Lederle. Indeed, the record shows just the opposite. The FDA's information-gathering mechanisms

were pervasive even in the 1960s—they reached into the experiences of manufacturers, hospitals, and doctors' offices. *See* Ruge, *supra*, 32 *Law & Contemp. Probs.* at 659-60. The evidence had not yet convinced the FDA; that does not mean that it was concealed from the FDA.

## III

The exclusion of Declomycin from the original list of tetracycline analogues that had to carry a label warning against tooth staining was not merely "an unfortunate turn of events." *Ante* at ___ (slip op. at 48). It was a deliberate administrative response by the FDA. Available information did not substantiate such a labeling requirement.

The Court's single-case focus inevitably diverts any risk-benefit analysis away from the proper medication-market balance to an improper medication-patient one. Unlike cigarette cases, in which the offending substance provides neither society nor the individual with any appreciable medical benefit, pharmaceutical cases demand the most accurate risk assessment possible:

> [I]n the event that the tort system fails to assess appropriately the relative risk calculus, and thereby deters the development, forces the removal, or skews the pricing of medications that lower aggregate harm, certain individuals will be unable to receive net beneficial medications. As such, total harm will increase. * * * Although the tort system undeniably provides the only compensation for some individuals, tort law in the pharmaceutical context distorts the availability and price of beneficial medications, thereby harming more individuals in the first instance.
>
> [Note, *Pharmaceutical Regulation*, *supra*, 103 *Harv. L. Rev.* at 784-85.]

Announcing such fears is neither crying wolf nor aping Chicken Little. "The histories of Oculinum, Bendectin and

DPT vaccine symbolize a developing crisis in health care." *Id.* at 775. The manufacturers of Oculinum could not obtain insurance on the drug, and hence it could not be marketed, despite six years of experimental success in treating eye problems. *Id.* at 774; *see also Brown, supra*, 44 *Cal.*3d at 1065, 751 P.2d at 480, 245 *Cal. Rptr.* at 421 ("a manufacturer was unable to market a new drug for the treatment of vision problems because it could not obtain adequate liability insurance at a reasonable cost"). The story of Bendectin illustrates how net health benefits can be evaporated by non-expert juries without any demonstrable basis.

> Bendectin is a drug effective in remedying the difficulties of morning sickness. The drug continues to enjoy the approval of the FDA, and studies have consistently concluded that the drug is safe. Nonetheless, Bendectin became such a popular target for tort lawsuits alleging that it was responsible for birth defects that the drug's manufacturer withdrew it—the only available morning sickness medication—and submitted to a $120 million class action settlement. Although the manufacturer had not lost a case on appeal, "[s]ince even wins were only adding to the costs of defense, the company * * * decided to settle."
>
> [Note, *Pharmaceutical Regulation, supra*, 103 *Harv. L. Rev.* at 774 (quoting "Morning Sickness, Legal Miscarriage," N.Y. Times, July 30, 1984, at A20, col. 1).]

The diphtheria-pertussis-tetanus (DPT) vaccine saga is a bit more complicated but no less revealing. At one time, pertussis, or whooping cough, "was a major cause of childhood morbidity and mortality in the United States." Note, *A Vaccine Manufacturer's Defense, supra*, 56 *U. Mo.-K.C. L. Rev.* at 519. It caused 36,013 deaths and over 800,000 cases between 1926 and 1930. *Ibid.* Because of the development and use of an effective vaccine, no more than 3,000 cases a year, and between five and twenty deaths

a year, were reported from 1960 to 1982. However, the disease may ravage our children again—"skyrocketing litigation costs," *id.* at 516, prompted seven of the eight DPT vaccine manufacturers to withdraw from the market and caused the price per dose to rise from 11¢ to $11 between 1981 and 1986. Note, *Pharmaceutical Regulation*, *supra*, 103 *Harv. L. Rev.* at 775 n.10; *see also* Viscusi & Moore, "Rationalizing the Relationship Between Product Liability and Innovation," P. Schuck, *supra*, at 111. ("Rising liability costs" caused ten of the thirteen manufacturers of vaccines for five serious childhood diseases to cease production between 1981 and 1990). These are events with which we are familiar. *See Schackil v. Lederle Laboratories*, 116 *N.J.* 155, 178-80 (1989). Drug manufacturers refused to supply a newly discovered vaccine for influenza on the ground that mass innoculation would subject them to enormous liability. The government therefore assumed the risk of lawsuits resulting from injuries caused by the vaccine. *See Feldman v. Lederle Laboratories*, 189 *N.J. Super.* 424, 435-36 (App. Div. 1983); Franklin & Mais, *Tort Law and Mass Immunization Programs*, 65 *Calif. L. Rev.* 754, 769 (1977).

The majority's view of the issue of "what choices, if any, did Lederle have in 1962 and 1963," *ante* at ___ (slip op. at 46), demonstrates its failure to understand the importance of risk utility analysis in the development and marketing of prescription drugs. It determines that Lederle could have discontinued the production or raised the price to cover its potential liability. Ignored entirely in the majority's assessment is the effect the drug's removal from the market or its increased price will have on the numerous people who are helped by the drug. The majority does not consider the good the drug does, the lives it may save, or the suffering and pain it may prevent. The majority's suggestion that suspending production or raising the price of Declomycin in response to then-unverified possibilities ignores the widespread disutility of such practices,

especially if the possibilities proved to be false alarms. Drugs would go unproduced or produced only at high prices: each prevents many in need from using them.

That is not an unrealistic appraisal. To assume or posit, as the majority does, that tort liability judgments do not have a profound regulatory effect on the prescription drug market is naive. As noted by the California Supreme Court, "the possibility that the cost of insurance and of defending lawsuits will diminish the availability and increase the price of pharmaceuticals is far from theoretical." *Brown, supra*, 44 *Cal.*3d at 1064, 751 P.2d at 479, 245 *Cal. Rptr.* at 421; *see also id.* at 1065, 751 P.2d at 480, 245 *Cal. Rptr.* at 421 (rejecting a failure-to-warn claim for the "same reasons of policy" that led court to reject strict liability). In *Shackil v. Lederle Laboratories*, we recognized the "important societal goals of maintaining an adequate supply of life-saving vaccines and of developing safer alternatives to current methods of vaccinations." 116 *N.J.* at 190. In finding for the defendant, we stated that "our aim is not to insulate vaccine manufacturers from liability, but to acknowledge a painful reality—that the excessive exposure to liability * * * would inevitably discourage highly useful activity." *Id.* at 190-91. Whatever the validity of the "incidental effects" distinction of *Dewey, supra*, 121 *N.J.* at 90-94, the examples of Oculinum, Bendectin, and DPT vaccine demonstrate that the prescription-drug market has directly felt the regulatory effect of the threat or payment of court-awarded damages. *Brown, supra*, 44 *Cal.* 3d at 1064-65, 751 P.2d at 479, 245 *Cal. Rptr.* at 421 (noting 300% increase in cost of Bendectin and "hundredfold" increase in price of DPT vaccine that parallelled increase in lawsuits from one in 1979 to 219 in 1985).

> [T]he tort system undermines the availability of pharmaceuticals. Even in the absence of liability judgments, the mere fear of astronomical liability may render a drug uninsurable and consequently unmarketable. In the event that a beneficial drug does reach

> the market, but becomes the target of tort suits, litigation costs alone may force the manufacturer to withdraw its product. Moreover, actual or potential tort liability, even if it does not force the removal of a medication from the market can have marked effects on pricing and production.
>
> [Note, *Pharmaceutical Regulation*, *supra*, 103 *Harv. L. Rev.* at 774-75.]

Awarding compensatory damages certainly does have a regulatory effect. *See Shackil*, *supra*, 116 *N.J.* at 190-91; *see also* Ackerman, *supra*, at 93 (if manufacturers surpass "the optimal agency standard" of care because of fear of damage awards, "marginal costs" of production will "exceed marginal benefits," producing "regulatory effect" from "purely compensatory damages").

Congress empowered the FDA alone to set that "optimal" level—*i.e.*, to make the necessary risk/benefit analysis involved in the marketing of prescription drugs. Congress understood that "there is no such thing as absolute safety in drugs." *Hearings on Drug Safety Before the Subcomm. on Intergovernmental Relations of the House Comm. on Government Operations*, 88th Cong., 2d Sess. 147 (1964) *quoted in* Note, *Pharmaceutical Regulation*, *supra*, 103 *Harv. L. Rev.* at 773. Yet, Congress created and continued to support the FDA's regulatory approach. That approach calls for extensive pre-marketing testing and risk/benefit evaluation. It also demands that post-marketing information be gathered. That post-marketing information, however, will warrant a withdrawal or a conditioning of a drug's continued approval only if there is substantial evidence demonstrating the necessity of such action. That is an administrative decision based on a desire to increase the aggregate health benefits, and on a legitimate *ad hoc* risk assessment that holds that once an already-approved drug has proven sufficiently safe and efficacious in premarket studies, the interest in health demands that it not

be withdrawn or encumbered until a certain amount of evidence exists.

A system in which we shun expertise, experience, and institutional purpose and instead allow a court to change drug labels after it "arrogates to a single jury the regulatory power explicitly denied to all the fifty states' legislative bodies" seems strange. *Fitzgerald v. Mallinckrodt, Inc.*, 681 F. Supp. 404, 407 (E.D. Mich. 1987). Moreover, jury verdicts discourage the use of important drugs. Through the media, the public becomes aware of jury verdicts that frighten, and focuses its attention on the side-effects of the drug without any appreciation of its beneficial results.

## IV

Lederle proposed a change in the labeling of Declomycin to warn of possible tooth staining in November 1962, but the FDA did not believe that the evidence warranted such a change and refused to authorize it. In *Feldman* I, we wondered if "it would [not] seem anomalous for the FDA to have prevented a drug manufacturer from advising the public immediately of a newly discovered danger while waiting for FDA approval." 97 *N.J.* at 459. However, the more substantial record provided by this case demonstrates that there is nothing at all anomalous about the FDA's position—there was no "newly discovered danger"; there was only a newly-suspected one.

In reviewing Lederle's November 1962 request to change the labeling of its tetracycline drugs to warn of possible tooth discoloration, the FDA balanced the substantial therapeutic benefits that those drugs had in the treatment of a wide range of bacterial infections against the scientifically-knowable risks of tooth staining in normal, healthy children. The FDA also considered the impact that that warning—if the suspicions about Declomycin proved to be unfounded—would have on rational prescribing and on the

credibility of side-effect warnings generally. As stated by Dr. Barzilai of the FDA in his December 3, 1962, letter acknowledging Lederle's desire to change its Declomycin label, the issue had to be reviewed from a "medical, scientific [and] regulatory" point of view before the FDA could reach "any form of final opinion" on the matter.

What has happened in this case is that a lay jury was instructed by the trial court to second-guess freely those delicate scientific and policy judgments of the FDA from a vantage point twenty-five years later. The logic of giving judicial deference given to the medical judgments of the FDA and the agency's own view of its statutory role in the drug-labeling process is even more compelling when the issue is the liability of an FDA licensee who has strictly complied with the agency's dictates, as occurred here.

The FDA, not courts, must determine the proper balance of risk and benefit and the necessary extent of any warnings. To make such broad judgments is peculiarly beyond the competence of courts. The FDA, not the courts, has the assets and abilities both to protect and to promote health. Indeed,

> [s]ince 1938, Americans have looked to the FDA for assurance of quality in the medicines they take. Pursuant to this task, the FDA has developed the highest level of competence in pharmaceutical investigation in the world. Nevertheless, technically incompetent state court juries are continuing to usurp federal authority by rejecting FDA standards in product liability cases.
>
> [Comment, *Federal Preemption, supra*, 22 *J. Marshall L. Rev.* at 656.]

Many battles remain to be fought—for example, the fight against AIDS. *See* McKenna, *The Impact of Product Liability Law on the Development of a Vaccine Against the AIDS Virus*, 55 *U. Chi. L. Rev.* 943 (1988). "Drug availability and pricing policies may depend on the ability of

manufacturers to limit their own liability. The consequences of these issues extend beyond the AIDS epidemic and influence the extent to which the drug development process will be able to respond to disease victims in the future." Comment, *Legal Concerns for Manufacturers*, *supra*, 139 *U. Pa. L. Rev.* at 1078. Those problems convince me we would be better to trust the decisions made by experts at the FDA rather than by health novices, such as jurors or judges.

"[I]mplicit in any decision to broaden liability in order to provide compensation is a judgment that the goals of public policy will likewise be served." *Shackil*, *supra*, 116 *N.J.* at 177. By holding Lederle liable despite its strict adherence to federal law, as understood and applied by the FDA at the time and despite Lederle's efforts quickly to bring to the attention of the FDA, all the information it had, and despite its cooperation in providing the public with all relevant, pharmacologically-significant, and verified information at the earliest possible date, the majority thwarts the important "societal goals [of] encouraging the use and development of needed drugs * * * in order to provide compensation to those injured by [Lederle's] products." *Id.* at 178.

Conveying useful, important information on drug labeling promotes a vital societal need: the safe and efficacious use of drugs. However, "[t]o permit or require statements of conflicting opinion on all these matters would destroy the present usefulness of prescription drug labeling." 39 *Fed. Reg.* 33,232 (1974). That statement shows that the FDA does not establish minimum standards—it establishes uniform ones. Today's decision requires a warning that the FDA would not permit. In early to mid-1963, available scientific knowledge had not reached a level that allowed Lederle or the FDA to present anything other than a "conflicting opinion" regarding the potential effect of Declomycin on developing teeth. Because requiring or

permitting such deviation "would destroy the present usefulness of prescription drug labeling," *ibid.*, I cannot join my colleagues.

V

Based on my analysis, a discussion of *N.J. S.A.* 2A:58C-4 is not necessary. Nonetheless, I add a few comments to indicate my disagreement with the majority's analysis of that statute.

The Legislature enacted *N.J.S.A.* 2A:58C-4 in a regulatory system that allows manufacturers to make conditional label alterations and additions. The effort to create a pro-manufacturer presumption evinces legislative recognition of precisely the concerns I have discussed throughout this opinion. Indeed, the primary motivating force behind *N.J.S.A.* 2A:58C-4 was an effort to restore some protection to a manufacturer's decision to conform to FDA labeling decisions, a protection stripped by overly-enthusiastic judicial expansions of the reasonable implication of the FDA's 1965 regulatory amendments. To carry out the goals of *N.J.S.A.* 2A:58C-4, the Legislature "establish[ed] clear rules," *Senate Judiciary Committee Statement, L.1987, c.197, 202nd New Jersey Legislature, 2d. Sess., reprinted in* 1987 *New Jersey Session Law Service (No. 6)* 193, 194, created a strong presumption in favor of FDA decisions, *N.J.S.A.* 2A:58C-4, and limited the costs of litigation, *see N.J.S.A.* 58C-5(c) (exempting FDA-approved drugs from punitive damages). All those goals undercut and contradict the majority's decision.

Moreover, the majority's analysis of the specific facts of this case is flawed. Preemption in this case presupposes the pre-1965 world in which Lederle could not have changed its Declomycin label in any way without prior FDA approval, whereas the statutory presumption presupposes the post-1965 world in which Lederle has a limited freedom to make conditional alterations or additions

pending a dispositive FDA ruling. The majority draws from that distinction the conclusion that

> under the unique circumstances of this case, compliance with the "determination" of the FDA not to require a warning for Declymycin due to the lack of "unequivocal factual evidence of adverse reaction in man," although evidence of the adequacy of the labeling, should not be accorded the same presumptive weight now given to warnings approved or prescribed by that agency, and certainly does not create a conclusive presumption that the labeling contained an adequate warning.
>
> [*Ante* at ___ (slip op. at 52.]

I agree—it should be given more.

Today's manufacturers have the limited freedom to enhance the warning they give. Concomitantly, they can be held accountable for failure to exercise that freedom when it would have been reasonable to do so. Seeking "to establish clear rules with respect to specific matters as to which decisions of the courts in New Jersey have created uncertainty," *Senate Judiciary Committee Statement, Senate No. 2805 - L.1987. c.197, supra, reprinted in* 1987 *New Jersey Session Law Service (No. 6)* at 194, the Legislature made it presumptively reasonable not to exercise that freedom to enhance a label already approved by the FDA. A pre-1965 manufacturer had no similar freedom. Consequently, it could not be held liable for failure to exercise a then-non-existent freedom. In that context, the presumption is so strong we call it preemption.

SUPREME COURT OF NEW JERSEY

No. A-93 September Term 1990

On appeal from

On certification to Appellate Division, Superior Court

CAROL ANN FELDMAN,
Plaintiff-Appellant,

v.

LEDERELE LABORATORIES, a Division of American Cyanamid Company, a Maine corporation doing business in the State of New Jersey,
Defendant-Respondent.

Decided July 24, 1991

Chief Justice Wilentz Presiding

Opinion by Justice Clifford

Dissenting opinion by Justice Garibaldi

| CHECKLIST | Affirm | Reverse & Remand | Dissent | Concur in Result |
|---|---|---|---|---|
| Chief Justice Wilentz | | X | | |
| Justice Clifford | | X | | |
| Justice Handler | | X | | |
| Justice Pollock | | X | | |
| Justice O'Hern | | X | | |
| Justice Garibaldi | | | X | |
| Justice Stein | | X | | |
| TOTALS | | 6 | 1 | |

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APPROVAL OF THE COMMITTEE ON OPINIONS

SUPERIOR COURT OF NEW JERSEY
APPELLATE DIVISION
A-270-86T7

CAROL ANN FELDMAN,
Plaintiff-Respondent
and Cross-Appellant,

v.

LEDERLE LABORATORIES, a Division of American Cyanamid Company, a Maine corporation doing business in the State of New Jersey,
Defendant-Appellant and
Cross-Respondent.

Argued January 31, 1989 - Decided July 13, 1989

Before Judges Michels, Muir, Jr. and Keefe.

On appeal from the Superior Court, Law Division, Essex County.

William C. Slattery argued the case for the appellant and cross-respondent Lederle Laboratories, a Division of American Cyanamid Company (Morgan, Melhuish, Monaghan, Arvidson, Abrutyn & Lisowski, attorneys; and Norris, McLaughlin & Marcus, of counsel; James L. Melhuish and William C. Slattery, of counsel and on the brief; Scott Friedman, Michael K. Tuzzio, Kevin E. Wolff, Robert S. Corcoran, on the brief).

James I. Peck, IV, argued the case for the respondent, cross-appellant.

Marc S. Klein argued the case for the *amici curiae*, Pharmaceutical Manufacturers Association and E.R. Squibb & Sons, Inc. (Sills, Beck, Cummis, Zuckerman, Radin, Tischman & Epstein, attorneys; Charles J. Walsh, Marc S. Klein, Bruce J. Brennan, Geoffrey R.

W. Smith, Howard L. Dorfman, of counsel and on the brief).

The opinion of the court was delivered by KEEFE, J.S.C. t/a

In this failure to warn product liability case, defendant Lederle Laboratories (Lederle), a division of American Cyanamid Company, appeals from an adverse jury verdict in favor of plaintiff, Carol Ann Feldman.[1] The general theory of liability presented by plaintiff at trial was that Lederle's product, Declomycin, was defective in the years 1960 through 1963 because it lacked a warning that its ingestion by young children might result in tooth staining. Lederle argues on appeal that plaintiff's failure to warn claim is preempted by federal law. Alternatively, Lederle argues that certain trial errors regarding evidence matters and jury instructions require a new trial.[2] By leave of court, Pharmaceutical Manufacturer's Association and E.R. Squibb & Sons, Inc. filed a brief as *amici curiae*, joining in Lederle's preemption argument. *Amici* also argue that imposing liability on Lederle under the facts of this case

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[1] This case has had a lengthy and arduous legal history. At the first trial of this case in 1980, the jury returned a verdict in favor of Lederle. The plaintiff's motion for a new trial was denied and she appealed. The Appellate Division affirmed *per curiam* in an unreported opinion. Plaintiff's petition for certification was granted and the Supreme Court remanded the matter to the Appellate Division for reconsideration in light of *Beshada v. Johns-Manville Products Corp.*, 90 *N.J.* 191 (1982). *Feldman v. Lederle Laboratories*, 91 *N.J.* 266 (1982). The Appellate Division affirmed again, this time in a reported decision. *Feldman v. Lederle Laboratories*, 189 *N.J.Super.* 424 (App.Div. 1983). A second petition for certification was granted. *Feldman v. Lederle Laboratories*, 94 *N.J.* 594 (1983). The Court reversed and remanded the matter to the Law Division for a new trial. *Feldman v. Lederle Laboratories*, 97 *N.J.* 429 (1984). It is this second trial that is now before us for consideration.

[2] Although plaintiff filed a notice of cross-appeal her brief did not address any issues raised in the notice. We were advised at oral argument that she has abandoned those claims.

conflicts with the public policy considerations underlying New Jersey's product liability law.

We conclude that the Food and Drug Administration's (FDA) regulation of the drug industry does not warrant a finding of implied federal preemption of all State tort claims grounded in strict liability failure to warn. However, under certain circumstances, such as presented here, federal law may preempt a discrete issue upon which liability is predicated because compliance with State decisional law would require federal law to be violated. Thus, plaintiff's entire cause of action was not preempted. However, the theory of liability not preempted was decided adversely to plaintiff by the jury and is not challenged on appeal, while the theory of liability which undergirded the jury verdict against Lederle was preempted by federal law. Thus, Lederle's motion for judgment notwithstanding the verdict should have been granted. Because the preemption issue resolves this appeal we do not address the other issues raised by Lederle.[3]

Plaintiff was born in February, 1960 and alleges that she was treated with Declomycin produced by Lederle during the period from her infancy into her fourth year. Declomycin is one of a group of tetracycline containing drugs which are broad spectrum antibiotic analogues used to combat bacterial infections.[4] Plaintiff's father, Dr. Harold Feldman, prescribed the medication for plaintiff in order to treat various illnesses. He was introduced to Declomycin by a Lederle medical representative in approximately 1959 when it was first marketed. Lederle had recommended the drug for pediatric use in its product labeling during the years 1960 through 1963 inclusive.

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[3] Our failure to address the alternative issues should not be understood to mean that they have no merit. Indeed, we perceive several errors in the jury instructions and evidentiary rulings which, but for our ruling on preemption, would require a reversal and new trial.

[4] The generic name for Declomycin is demethylchloretetracycline.

No medical records were kept by Dr. Feldman of plaintiff's treatment. However, he testified that he first gave the drug to his daughter approximately two to three months after her birth and continued to administer it until 1963, or possibly 1965.[5] Regardless of the time period, the doctor stated that he administered Declomycin only a total of eight to ten times over this period because the plaintiff was generally healthy. In 1965, Dr. Feldman noticed that his daughter's teeth were stained a shade of grey. He took her to Dr. Sachs, the family dentist, to learn the cause and was then informed of the correlation between tetracycline and tooth staining.

Dr. Milton Houpt testified as an expert in pediatric dentistry for the plaintiff. He examined her in January, 1985 and concluded that her teeth had been stained by tetracycline. The doctor testified that the staining on plaintiff's teeth was possibly consistent with tetracycline administration until the age of six or seven.

Dr. Feldman testified that in the 1960's, in addition to relying on the Lederle detailmen and package inserts, he relied on the Physician's Desk Reference (PDR) for information about Declomycin. The PDR did not contain a warning concerning tooth staining until 1965, although package inserts and other literature were changed in December, 1963.

In 1975, Dr. Feldman wrote a letter of inquiry to Lederle Laboratories concerning the staining problem. He received a reply from Lloyd S. Carr, Lederle's product's service manager. The letter, dated November 6, 1975, stated that, after "the causal relationship between tooth staining and tetracycline became unquestionably demon-

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[5] Plaintiff's amended complaint, filed after the remand for a new trial, alleged that she was administered the medication during 1960-1963. She has limited her claim that the product was defective to those years.

strated," Lederle notified the FDA in November, 1962 requesting permission to place a warning on the drug. The letter noted that Declomycin was specifically excluded by the FDA in April, 1963 from the requirement imposed on other tetracyclines to contain a warning concerning tooth staining. It further stated that in or about May, 1963, Lederle informed the FDA that Declomycin was also implicated in reports of tooth staining. Lastly, it said that a warning for Declomycin was approved by the FDA in December, 1963 and appeared in the PDR in 1965.

Plaintiff's theory was that Lederle knew or should have known of the side effects before 1962. Her proofs on that issue were substantially based on two articles co-authored by Dr. Harry Shwachman. The articles were entitled "The Tetracyclines, Applied Pharmacology" and "The Effect of Long Term Antibiotic Therapy in Patients With Cystic Fibrosis of the Pancreas." Dr. Shwachman, a specialist in cystic fibrosis, testified on behalf of plaintiff by way of a *de bene esse* deposition. He related conversations he had with Dr. Carey, the deceased former medical director of Lederle, in which Dr. Shwachman told Dr. Carey about the "problem of staining of the teeth" he had encountered in using tetracyclines to treat children with cystic fibrosis. However, Dr. Shwachman admitted that both articles, published in 1956 and 1958, were inconclusive as to the cause of the observed tooth staining and were based solely on work with cystic fibrosis patients who were treated with the tetracycline drugs on a daily basis over a long period of time. Further, none of this work involved Declomycin, which was introduced in 1959.

In a letter dated January 10, 1963, addressed to Roy Schaefer at Lederle, Dr. Shwachman detailed his findings, at Schaefer's request, concerning tooth staining in cystic fibrosis patients up to that point in terms of age versus dosage. The letter revealed an apparent correlation between tetracyclines and tooth staining without drawing any real conclusion. As stated in the letter by Dr. Shwach-

man, "[t]he study is still being continued and I think that the specific answer to your questions will become obvious in due course of time."

Dr. Swanzey, who had been employed by Lederle in the 1960's, was called as plaintiff's witness and examined concerning the Shwachman articles. He testified that both of the articles were in the possession of the defendant in 1960. Each article contained a notation to the effect that tooth staining had been observed in cystic fibrosis patients who were treated with tetracyclines. He noted that both articles had been written in the 1950's, before Declomycin was marketed. Thus, Declomycin was not the tetracycline containing product referred to in either article. Dr. Swanzey stated that, even after the publication of the second study, it was not clear whether the tooth staining was due to the drug or the disease of cystic fibrosis. To Dr. Swanzey's knowledge, no comparative study was done on the teeth of cystic fibrosis patients who had received tetracycline versus those who had not to determine if the discoloration was due to the antibiotics or the disease itself.

Defendant presented Doctors Guggenheimer, Sweeney, and Wasserman to testify concerning the state of scientific knowledge in the relevant time period. Dr. Guggenheimer, a dentist and professor of dentistry, opined that there was no information available suggesting a relationship between the administration of tetracyclines and tooth discoloration in 1960 and 1961. He testified that reports began to appear in 1962 which raised questions as to whether there was a relationship between tooth discoloration, cystic fibrosis and the tetracyclines, but the medical investigators "could not come to any conclusion as to what exactly was going on." The doctor cited an editorial in The New England Journal of Medicine in 1963 which "indicated that more evidence was needed as to what exactly the mechanism [for discoloration] was and why this was occurring." The apparent reason for the confusion was that all children with stained teeth were also cystic fibrosis patients. Dr.

Guggenheimer said it was impossible to separate the two phenomena. The doctor had participated in animal studies at Columbia University in the early 1960's to attempt to answer this question but could not do so because no significant effect could be found at that time on the teeth of animals. When asked his opinion regarding Declomycin, Dr. Guggenheimer said:

> Since that particular antibiotic was, I believe, introduced in 1959, by 1963 there would—it would not be possible to identify it as a cause of tooth discoloration because any person receiving the antibiotic in 1959, their permanent teeth would not have yet appeared in 1963. The earliest that would be come evident would be approximately 1965.

He concluded that, with regard to Declomycin, Lederle could not have known of the correlation until after 1963.

Dr. Sweeney, a dentist educator, testified that prior to 1962 Lederle could not have known "in any way, shape or form" that the use of tetracyclines resulted in stained teeth. The doctor noted that only three or four papers had been written on the subject in that time frame and they were inconclusive. In his opinion, 1962 was a critical year because evidence began to indicate that the teeth of children other than cystic fibrosis patients might be affected by tetracyclines. Dr. Sweeney felt that Lederle should have known there was a problem with Auromoycin and Acromycin in 1963, but not Declomycin, because there were no reports in 1963, or earlier, pertaining to Declomycin.[6] Dr. Wasserman, a pediatrician and professor of medicine, also testified that there was insufficient infor-

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[6] The generic name for Acromycin is tetracycline. The generic name for Auromycin is chlortetracycline. However, there was a tendency to refer to all of these antibiotic analogues, including Declomycin, as tetracycline drugs.

mation about the possibility of tooth discoloration from the use of tetracylcines through 1963.

Plaintiff offered a three page Lederle Laboratories District Manager Weekly Report, dated August 18, 1962, as further proof of Lederle's knowledge. The report read in part:

> We are beginning to hear comments about the yellowing discoloration of teeth in children following tetracycline therapy. One physician, already reported to Pearl River, [Lederle's home base] also states his own children's second teeth are soft following tetracycline therapy. This physician states he will discontinue using tetracyclines until this phenomenon is proved or disproven.

In October, 1962, Dr. Swanzey and his associates began to compose a warning concerning tooth staining caused by tetracycline drugs for submission to the FDA. On November 16, 1962, Dr. Swanzey wrote a letter to the FDA concerning the possibility of a correlation between tooth discoloration and Lederle's tetracycline drugs. In the letter, Lederle proposed to warn of the phenomenon in terms of all its tetracycline products. Lederle submitted its proposed warning language and asked for the FDA's "opinion and consideration" so that this statement could "be added at the earliest possible time." On December 3, 1962, Dr. Barzilai, medical officer, Division of Antibiotic Drugs, Bureau of Medicine of the FDA, replied to Dr. Swanzey's letter. Dr. Barzilai stated that the FDA had "not yet reached any form of final opinion (= medical, scientific, regulatory, etc.),. . ." He concluded by informing Dr. Swanzey that the FDA was currently "devoting a great deal of active attention to the matter and [would]. . .notify as soon as any conclusion is reached."

In February, 1963, Dr. Barzilai wrote to Dr. Swanzey advising him that the FDA had approved the warning to

be asserted in the printed material of "all [Lederle's] tetracycline products. . . ." On February 14, 1963, Dr. Swanzey, in acknowledging receipt of the FDA's letter with the approved warning language for all tetracycline drugs, wrote to the FDA, stating "I assume that this statement is being proposed for chlortetracycline, oxytetracycline[7] and demethylchlortetracycline [Declomycin] as well."[8]

On February 18, 1963, Dr. Barzilai replied to Dr. Swanzey's inquiry and stated that the warning had to appear in the labeling of only tetracylcine, chlortetracycline, and oxytetracycline. Dr. Barzilai further stated, "[t]here is practically no specific clinical evidence to substantiate such a labeling requirement for demethylchlortetracycline [Declomycin] at present, but we intend to remain alert for such a future possibility."

On April 18, 1963, the FDA issued a press release to all medical and dental journals, and to the general media, with respect to tooth discoloration and tetracyclines. The release stated in pertinent part:

> Children's teeth can be seriously discolored by three types of tetracycline antibiotics, the Food and Drug Administration said in a message to physicians and dentists.
>
> The three drugs are: tetracycline, chlortetracycline and oxytetracycline. There is no evidence to date that a fourth drug, [declomycin], causes the discoloration, FDA said.

On April 23, 1963, Lederle issued an "Action" memorandum to all Lederle sales personnel. The purpose of the

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[7] The brand name for oxytetracycline was Terramycin.

[8] It would appear that Dr. Swanzey's inquiry was necessary because Dr. Barzilai used only the word tetracycline in his correspondence rather than the generic names of Lederle's other products that were analogues of tetracycline.

memo was to advise the sales people of the latest information concerning FDA requirements for antibiotic literature, and its specific subject was tooth staining. The memo told the salesmen that inserts would be sent to them shortly for inclusion with all of the tetracycline based drugs except Declomycin. Further, the memo told the salesmen not to capitalize on the fact that Declomycin had been excluded from FDA warnings because Declomycin would probably soon be implicated in staining and require warnings as well.

On May 8, 1963, Dr. Swanzey wrote to Dr. Barzilai to bring the FDA up to date on additional information concerning the subject of tooth discoloration that had come into Lederle's possession since Swanzey's last correspondence. Enclosed with that letter was an article printed in the June, 1962 issue of the Canadian Medical Association Journal, together with another document which quoted from the first, suggesting that Declomycin was associated with tooth discoloration and looseness of finger nails.

On May 31, 1963, Commissioner Larrick of the FDA wrote to Dr. Swanzey and explained why the warning approved by the FDA for tetracycline products specifically exclude Declomycin. He said:

> Actually, the original statement was revised to require the inclusion of the name of the drug in lieu of the word "tetracyclines" because to date we have no evidence that your drug [Declomycin] will stain teeth. If the warning statement as originally proposed is used, it automatically incriminates [Declomycin].

On July 1, 1963, Dr. Barzilai replied to the May 8, 1963 letter from Dr. Swanzey and said that the FDA had reviewed all of the Declomycin adverse incident reports and other information supplied by Lederle but that it could not "as yet justify any change in our current formal position on this matter."

On November 8, 1963, in a telephone conversation between Kevin Rooney of Lederle and Dr. Barzilai that was later confirmed in a letter from Rooney to Barzilai on November 11, 1963, it was finally decided that Lederle would incorporate the tooth staining statement in all of the labeling for Declomycin products. Submission of the final form of the Declomycin tooth staining warning was made by letter to the FDA dated December 12, 1963.

The plaintiff's position, as stated earlier, is that Declomycin was defective in the years 1960 through 1963 because it lacked a warning concerning tooth staining during those years. It was in the context of the foregoing facts and plaintiff's theory of liability that the trial judge asked the jury to answer the following special interrogatory.

> Was there a defect in defendant Lederle's product, Declomycin, because it failed to warn of tooth discoloration?
>
> A. In 1960
> B. In 1961
> C. In 1962
> D. In 1963

The jury, in response to the above interrogatory, replied that Declomycin was not defective in either 1960 or 1961. In doing so it rejected plaintiff's argument that the articles authored by Dr. Shwachman and Lederle's own research should have put Lederle on notice of the dangers of tooth staining with respect to Declomycin before the time when Lederle itself became concerned about that side effect.

However, the jury found that the product was defective in 1962 and 1963. Specifically, with respect to Lederle's defense that it gathered sufficient information upon which to warn by the fall of 1962 but that FDA regulations required prior approval before a warning could be given and that FDA approval was not forthcoming, plaintiff's counsel argued in summation:

Lederle Laboratories could have warned of tooth staining resulting from Declomycin administration in November of 1962. In fact, it could have warned in October of 1962 because you heard Dr. Swanzey say "Well, look, here is a paper dated October of 1962 which has a warning that I divvied up for proposal to the F.D.A." So for 13 months they waited for no reason while kids were getting Declomycin, along with this kid. In those 13 months Dear Doctor letters could have been sent out. In those 13 months some ads could have been placed in the Journal of the American Medical Association or any like professional journal. During those 13 months the detailmen could have been sent out with specific instructions to tell doctors not to prescribe Declomycin for pediatric use.

. . .

Why Lederle waited 13 months to warn on Declo is for you to surmise, it is not for me to suggest. There is no evidence one way or the other as to why they waited, ladies and gentlemen, aside from the alleged trade practice of getting F.D.A. approval first on warnings. Trade practice; what other drug manufacturers do. If you find that a compelling reason for them to wait 13 months, then you can find against the plaintiff, you can find no cause for action; but if you find that there was no good reason for waiting those thirteen months, then I suggest you return a verdict for the plaintiff.[9]

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[9] This argument was undoubtedly based, in part, on testimony given by Dr. Swanzey at the current trial and the first trial. In essence, Dr. Swanzey said that he was unaware of any specific statute or regulation that required the FDA to give prior approval to label changes in the

In view of plaintiff's theory of liability pertaining to the years 1962 and 1963 as set forth in the closing argument and the trial judge's instructions to the jury that prior approval from the FDA was not required, we can only conclude that the jury determined liability against Lederle based on its failure to warn during the 13 month period that elapsed between November of 1962, when it first wrote to the FDA for permission to change its labeling, and December of 1963, when the FDA approved the label change and Lederle complied.

Plaintiff contends that the Supreme Court's decision in *Feldman v. Lederle Laboratories*, 97 *N.J.* 429 (1984) (*Feldman I*) precludes a discussion of preemption. We disagree. In *Feldman I*, the Court observed that Lederle raised the preemption defense for the first time before the Appellate Division. *Id.* at 458. However, we decided the appeal on other grounds and did not address preemption. *Feldman v. Lederle Laboratories*, 189 *N.J. Super.* 424 (App. Div. 1983), reversed 97 *N.J.* 429 (1984). Because the defense had not been raised at the trial level and had not been relied upon by us in deciding the case, the Supreme Court could have refused to entertain the issue. *Nieder v. Royal Indemnity Ins. Co.*, 62 *N.J.* 229, 234 (1973). When an appellate court recognizes that a case will be remanded for a new trial, it ordinarily "defer(s) discussion of the issue" not fully litigated in the first trial until a complete record is made. *Feldman*, 97 *N.J.* at 458. However, the Supreme Court, in this instance, elected to give the trial

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relevant time period but that it was the drug manufacturers' practice to do so. Dr. Swanzey hastened to add, however, that he was not an attorney, indicating his lack of expertise in statutory and regulatory interpretations. Whether prior approval by the FDA was required or simply trade practice was a matter of law, not a matter of lay opinion. However, in view of the trial judge's ruling that FDA approval was not required before changing the warnings, Dr. Swanzey's testimony to the effect that it was a trade practice was relevant on the issue of Lederle's reasonableness.

court guidance by making "comments" on the issue based on the information before it at the time. *Ibid.* Those comments constituted *dicta* because they were not necessary to the decision then being made. As such they are entitled to "due consideration but [do] not invoke the principle of *stare decisis.*" *Jamouneau v. Division of Tax Appeals*, 2 *N.J.* 325, 332 (1949). Prior decisions of this court have also concluded that *Feldman I* did not preclude a consideration of preemption in the context of FDA regulation of the drug industry. *Shackil v. Lederle Laboratories*, 219 *N.J. Super.* 601, 616, 634 (App. Div.1987), certif. granted 109 *N.J.* 519-520 (1987). See also, *McQuaid v. Burlington County Memorial Hosp.*, 212 *N.J. Super.* 472, 476 (n.1), (App.Div. 1986).

Plaintiff argues that, at the second trial of this matter, Lederle's proofs were "no more compelling, and scarcely more numerous, than what it introduced in 1980 or what it submitted by way of argument on first appeal." Lederle disagrees and lists the items placed in evidence at the second trial which were not in evidence at the first trial. They are: 1) the information relating to the possible side effects of Declomycin submitted by Lederle to the FDA subsequent to November, 1962 contained in its letters dated January 15, 1963 and May 8, 1963; 2) the letter from FDA Commissioner Larrick dated May 31, 1963; 3) the letter from Dr. Barzilai of FDA dated July 1, 1963; and 4) the FDA press release, dated April 18, 1963, sent to all medical and dental journals.[10] Clearly, the evidence on the preemption issue was different and more broadly developed at the second trial.

The Supreme Court in *Feldman I* emphasized the importance of a full factual development when it said:

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[10] Plaintiff's reply brief does not contest Lederle's assertion that the listed evidence was new evidence in the second trial.

> "Cases state principles but decide facts, and it is only the decision on the facts that is binding precedent." [97 *N.J.* at 455, quoting *Konrad v. Anheuser-Busch, Inc.*, 48 *N.J. Super.* 386, 388 (Law Div. 1958)].

The Supreme Court could not have foreseen at the time it wrote *Feldman I* that the jury would reject plaintiff's contention that Lederle knew or should have known of the tooth staining side effect prior to 1962 when Lederle admitted it first became aware of the relationship. Nor are we certain that the Court knew that plaintiff's argument at the re-trial, relative to Lederle's conduct in 1962 would be limited to Lederle's duty to warn without the FDA's prior approval and notwithstanding the FDA's refusal for 13 months to approve Lederle's request. For these reasons we feel that the Supreme Court has not foreclosed a consideration of the preemption defense raised by Lederle.

The concept of federal preemption is rooted in the Supremacy Clause of the federal Constitution. *U.S.Const.* Art. VI, cl. 2. State law that conflicts or interferes with federal law must yield because of this constitutional provision. State law which may conflict with federal law includes the state's common law. *International Paper Company v. Ouellette*, 479 *U.S.* 481, 107 *S.Ct.* 805 (1987). Likewise, federal regulations, such as those promulgated under the Food, Drug & Cosmetic Act of 1938 (FDCA), 21 *U.S.C.* §301, *et seq.*, have the same preemptive effect as federal statutes, as long as the federal regulations are within the framework of the enabling legislation and are not arbitrary. *Fidelity Fed. Sav. & Loan Assn. v. de la Cuesta*, 458 *U.S.* 141, 153-154, 102 *S.Ct.* 3014, 3022-23 (1982). Plaintiff does not contend that the federal regulations relied upon by Lederle were beyond the statutory authority of the regulatory agency to promulgate.

"Determining when . . . conflict or interference exists is frequently a complex and intricate matter. . . ." *U.S.A.*

*Chamber of Commerce v. State*, 89 *N.J.* 131, 141 (1982). It has been suggested by our Supreme Court that the "[p]reemption analysis begins with identifying the subject matter of the state law and determining whether there is a federal law operative in that field." *Id.* at 142. The decisional law of New Jersey holds that it is "unquestionably" the duty of a manufacturer, who markets a drug without warning of a danger of which it subsequently becomes aware, to communicate the "new warning" to "prescribing physicians as soon as reasonably feasible." *Feldman*, 97 *N.J.* at 456. The federal law operative in the same field is the FDCA, 21 *U.S.C.* §301, *et. seq.*, which is a thorough and comprehensive statute addressing the licensing, manufacture, sale and marketing of prescription drugs. Specifically, the statute prohibits the "introduction into interstate commerce of any . . . drug . . . that is . . . misbranded." 21 *U.S.C.* §331. Regulations promulgated by the Secretary of Health Education & Welfare (Secretary) and administered by the FDA pursuant to the statute address congressional concern for misbranding by establishing guidelines for product labeling, promotional literature and advertising. See generally, 21 *C.F.R.* §1.21.

Under the Supremacy Clause, federal law may supersede state law in several ways. First, Congress may preempt state law by stating its intention in express terms. Second, where express preemption cannot be found, Congress' intent to preempt state law may be inferred where the scheme of federal regulation is so comprehensive that it is reasonable to conclude congressional intent to regulate the field to the exclusion of state regulation. Thirdly, "[e]ven where Congress has not completely displaced state regulation in a specific area, state law is nullified to the extent that it actually conflicts with federal law. Such a conflict arises when 'compliance with both federal and state regulations is a physical impossibility,' *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 *U.S.* 132, 142-143, 83 *S.Ct.* 1210, 1217-1218, 10 *L. Ed.* 2d 247 (1963),. . . ." *Hills-*

*borough County, Fla. v. Auto. Med. Labs.*, 471 *U.S.* 707, 713, 105 *S.Ct.* 2371, 2375, (1985). Lederle concedes that express preemption does not apply in this case, and to the extent that Lederle argues that implied preemption exists, we disagree. However, for reasons that will be stated more fully herein, we conclude that "conflict preemption" applies to these rather unique facts.

"Conflict preemption" is also known as the "dual compliance test," and "concerns those state or local requirements that are incongruous with federal requirements; that is compliance with the State or local requirement causes the federal requirement to be violated, or vice versa." *Andrea v. Union Tank Car Co. Inc.*, 213 *N.J. Super.* 51, 62 (Law. Div., 1987), aff'd 216 *N.J. Super.* 219 (App.Div. 1987). An example of conflict preemption is provided by the case of *Southern Railway Co. v. Reid*, 222 *U.S.* 424, 32 *S.Ct.* 140 (1912). In that case a railroad declined to accept goods for shipment because rates for the required route had not yet been filed with the Interstate Commerce Commission as required under federal law. The plaintiff sued under a state statute requiring railroads to accept shipments whenever tendered and provided that, for the breach of this obligation, the shipper could recover "all damages actually sustained" together with a $50.00 a day "penalty". *Id.* at 431. The U.S. Supreme Court held that the state statute was preempted under federal law because it conflicted with federal requirements:

> If the regulation be not exclusive, this situation is presented: If the carrier obey the state law, he incurs the penalties of the Federal law; if he obey the Federal law, he incurs the penalties of the state law. Manifestly one authority must be paramount, and when it speaks the other must be silent. We can see no middle ground. [222 *U.S.* at 442, 32 *S.Ct.* at 144].

The explication of our conclusion that conflict preemption applies to this case necessarily begins with a review of the standards applicable to such an analysis. The United States Supreme Court recently said:

> [W]e have emphasized that in a situation where state law is claimed to be pre-empted by federal regulation, a "narrow focus on Congress' intent to supersede state law [is] misdirected," for "[a] pre-emptive regulation's force does not depend on express congressional authorization to displace state law." (citation omitted). Instead, the correct focus is on the federal agency that seeks to displace state law and on the proper bounds of its lawful authority to undertake such action. The statutorily authorized regulations of an agency will pre-empt any state or local law that conflicts with such regulations or frustrates the purposes thereof. [*City of New York v. FCC*, 486 U.S. ___, 108 *S.Ct.* 1637, 1642 (1988)].

Where compliance with federal regulation and state common law is "a physical impossibility," state law is nullified. *Fidelity Federal Sav. & Loan Ass'n v. de la Cuesta*, 458 *U.S.* 141, 155, 102 *S.Ct.* 3014, 3023 (1982). Justice Brennan expressed the U.S. Supreme Court's view on this point long ago when he said:

> A holding of federal exclusion of state law is inescapable and requires no inquiry into congressional design where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce,. . . . (citations omitted). [*Florida Avacodo Growers v. Paul*, 373 *U.S.* 132, 142-143, 83 *S.Ct.* 1210, 1217 (1963)].

Moreover, when inquiring into the design of the federal regulations it is not necessary to show that the agency specifically intended to preclude state decisional law.

Rather, the theory of conflict preemption turns on the effect that tort liability under state law would have on the federal regulatory scheme. See, *Palmer v. Liggett Group, Inc.*, 825 *F.2d* 620, 626 (1st Cir. 1987). Because the federal preemption doctrine is rooted in the Supremacy Clause of the U.S. Constitution, we are required to follow the U.S. Supreme Court's guidelines when analyzing such matters. See, *In re Application of Waterfront Comm. of N.Y. Harbor*, 35 *N.J.* 62, 68 (1961), *cert. denied* 368 *U.S.* 12, 82 *S.Ct.* 146 (1961).

Implied preemption does not occur simply because the FDCA and FDA regulate drug labeling, including advertisements and promotional material. Such an argument was rejected as overly broad and constitutionally unacceptable in *Hillsborough County, Fla. v. Auto. Med. Labs., Inc.*, 471 *U.S.* 707, 105 *S.Ct.* 2371, 2377 (1985). However, conflict preemption in the field of drug labeling has been found to be an acceptable way of accommodating federal and state interests. An example of the application of this narrower approach is found in a recent case involving the DPT vaccine. *Hurley v. Lederle Lab. Div. of American Cyanamid*, 851 *F.2d* 1536 (5th Cir. 1988), modified 863 *F.2d* 1173 (5th Cir. 1988). In rejecting the trial court's decision that plaintiff's cause of action was impliedly preempted by the pervasive federal regulation of drug warnings, the Circuit Court observed that the FDA:

> [A]ccepts information given by manufacturers proposing the licensing of a particular vaccine, and determines a proper warning based upon the information provided. 21 C.F.R. §§601.2, 601.12, 601.25. A state law determination on this issue should not be interjected to overrule the decision of the FDA. Such a procedure would place vaccine manufacturers in a position where they could not comply with both obligations. The FDA extensively regulates the contents and wording of these product inserts. *See, e.g.*, 21 C.F.R. §§1 and

> 201; 50 Fed. Reg. 51.108 (1985). A manufacturer must first provide all the relevant information to the FDA, which then determines a warning it deems appropriate. The manufacturer is required to print that precise warning in its product insert. *Id.* Most important, the manufacturers cannot change the language in the product insert without FDA approval. 21 C.F.R. §601.12. It would be patently inconsistent for a state then to hold the manufacturer liable for including that precise warning when the manufacturer would otherwise be liable for *not* including it. Thus, assuming that the FDA has processed all the relevant and available information in arriving at the prescribed warning, its decision as to the proper wording must preempt by implication that of a state. [*Id.* at 1179].

After concluding that the plaintiff's state tort claim was preempted, to the extent that state law made a manufacturer liable for including the precise warning required by the FDA, it said,

> [a] factual issue remains, however, as to whether the manufacturer provided the FDA all the necessary and available information on which to base the warning. Thus, the only question that can be presented to the jury consistent with the federal regulatory scheme is whether the manufacturer withheld, either at the time the FDA decided the content of the warning, or since then, information that would have changed the FDA's decision. [*Id.* 1179-1180].

While *Hurley* involves an interpretation of more recent federal regulations, it addresses the same issue presented by the facts of this case. We believe that the narrow approach to preemption exemplified by the *Hurley* decision properly acknowledges the "restrained view" required by

the U.S. Supreme Court in such instances. See, *Fidelity Federal Savings & Loan Ass'n v. de la Cuesta, supra*; *Silkwood v. Kerr-McGee Corp.*, 464 *U.S.* 238, 104 *S.Ct.* 615 (1984); See also, *Cippollone v. Liggett Group, Inc.*, 789 *F.2d* 181, 186-187 (3rd Cir. 1986); *cert. den.*, 479 *U.S.* 1043, 107 *S.Ct.* 907 (1987). (Holding that plaintiffs' suit against defendant tobacco companies were preempted only to the extent that plaintiffs' "state law claims 'actually conflict' with the Act. . . .")

We now focus on the legislative and regulatory scheme. With the adoption of the FDCA, Congress established a means for federal regulation of prescription drugs. The FDCA was "designed primarily to protect consumers from dangerous products . . . by applying the Act to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer." *United States v. Sullivan*, 332 *U.S.* 689, 696, 68 *S.Ct.* 331, 335-336 (1948). The Secretary of Health, Education and Welfare was initially charged with the responsibility for reviewing the safety of all new drugs prior to their marketing. No person could market a new drug unless an application to do so had been approved by the Secretary, at which time the application became "effective." 21 *U.S.C.* §355(a).

In 1945, Congress required additional pre-marketing approval procedures for antibiotics. (Declomycin is a prescription drug and an antibiotic). Antibiotics were not known in 1938 when the FDCA was enacted. When penicillin was first introduced, Congress recognized that antibiotics "are spectacularly efficacious in many serious diseases suffered by large numbers of our population." Federal Food, Drug and Cosmetic Act: *Hearings on H.R. 3151, H.R. 562, and H.R. 160 Before a Subcommittee of the House Committee on Interstate and Foreign Commerce*, 81st Cong., 1st Sess. 5-6 (1949). At the same time, Congress was concerned about the complications of the manufacture of such drugs and their safe use. Thus, it

determined to bring antibiotics "under even more stringent regulation" than regulations governing prescription drugs. *Pfizer, Inc. v. Richardson*, 434 *F.2d.* 536, 538 (2d Cir. 1970). Accordingly, Congress amended the FDCA to require that each batch of antibiotic and its labeling be certified by the FDA to "adequately insure safety and efficacy. . . ." 21 *U.S.C.* §357(a). Efficacy requirements were made applicable to other prescription drugs in 1963. See Pub. L. No. 87-781, 76 State. 780 (1962). The Secretary established the FDA as his agent to administer and enforce the FDCA.

Since Congress' overriding purpose in enacting the FDCA was to protect consumers from dangerous drugs and antibiotics, it specifically dealt with the warnings to physicians that must accompany them. Thus, the new drug application required, among other things, that the manufacturer supply the Secretary with "specimens of the labeling proposed to be used for such drug." 21 *U.S.C.* §355(b)(6). The application could be approved only if the Secretary found, among other things, that the labeling was not "false or misleading in any particular. . . ." 21 *U.S.C.* §355(d).

The concept of "labeling" is a broad one. It includes "all labels or other written, printed or graphic matter" upon the container of the drug, or which "accompany such article." 21 *U.S.C.* §321(m). Any information which "supplements or explains" the labeling is considered to "accompany such article" and thus is a part of the product's labeling. Physical attachment of the information to the product is not necessary. *Kordel v. United States*, 335 *U.S.* 345, 350, 69 *S.Ct.* 106, 109-110 (1948), *Reh. Den.*, 335 *U.S.* 900, 69 *S.Ct.* 298 (1948), *Reh. Den.*, 336 *U.S.* 911, 69 *S.Ct.* 513 (1949). Rather, the "textual relationship" of the communication to the article is the "significant" factor in determining whether the communication constitutes "labeling". *Ibid.* Thus, package inserts and all other communications to physicians with respect to the use or safety

of a drug are considered to be "labeling" subject to FDA approval.

Lederle supplied labeling to the FDA in 1959 in connection with its application to market Declomycin. The labeling did not contain a warning that the drug may cause tooth staining if administered to infants and young children. The FDA approved Lederle's application, and, thus, it must be implied that the FDA determined, "based on a fair evaluation of all material facts," that Lederle's labeling was not "false or misleading in any particular." 21 *U.S.C.* §355(d)(6). Plaintiff does not now contend that Lederle supplied either false or misleading information in order to secure FDA approval or failed to supply information that if supplied would have prevented such approval. Indeed, the jury's verdict finding no defect in the product in 1960 or 1961 precludes such an argument.

Because the jury found that Lederle's product was defective in 1962 and 1963, an analysis of the FDA regulations and procedures in effect in 1962 concerning changes in previously approved drug labeling, prompted by the post-marketing discovery of side effects, is critical to this appeal. One such regulation pertaining to labeling in connection with new drug applications provided:

> It is understood that all representations in this application regarding. . .labeling apply to the drug produced *until an effective supplement to the application provides for a change* or the article is no longer a new drug. [21 C.F.R. §130.4(c)(9), 21 Fed. Reg. 5579 (July 25, 1956). (emphasis added)].

As applied to the facts of this case, the wording of the regulation suggests that Lederle's approval to market Declomycin was conditioned upon no change being made in the labeling until an "effective supplement to the application" was processed.

Supplemental applications were expressly required by the FDA "if a material change [was] made in the . . .

labeling . . . from the representations in an effective application for a new drug," and if "the drug [was] marketed before a supplement [was] effective for such change, the [new drug] application may [be] suspended. . . ." 21 C.F.R. §130.9(a), 25 Fed. Reg. 12595 (December 9, 1960). "Labeling changes [included] deviations from the authorized brochures in *any* mailing or promotional pieces used after the drug is placed on the market." *Id.* (emphasis added). Conversely, a supplemental application was not required for changes in labeling that were "not significant from the standpoint of the safety of the new drug as established by the original new-drug application," but, even under those circumstances, the FDA had to be informed of the "proposed change or changes. . . ." Thereafter, the applicant was "notified in writing whether, in the Food and Drug Administration's opinion, the submission of a supplemental application [was] required for such change or changes. This include[d] all mailing and promotional pieces that [were] to be used after the new drug [was] placed on the market." 21 C.F.R. §130.9(b), 25 Fed. Reg. 12595 (1960).

Unlike other drugs, after the initial approval of an antibiotic, the antibiotic manufacturer was required to request certification of each batch before it was marketed. 21 C.F.R. §146.2 and 146.3 (1963). Before a batch could be certified, the FDA was required to find that the labeling did not contain any "untrue statement of a material fact," that it contained "all words, statements, and other information required by the regulations," and that it otherwise met all the statutory standards for adequate warnings. 21 C.F.R. §146.3 and 146.4 (1963). Furthermore, the regulations precluded antibiotic manufacturers from altering approved labeling in any respect without prior authorization because the certification of any batch of antibiotics ceased immediately to be effective if the "labeling [was] altered . . . in whole or in part, or cease[d] to conform to any labeling requirement. . . ." 21 C.F.R. §146.4(b) (2)

(1963). This included promotional labeling (advertisements, mailing and other promotional pieces) 31 Fed. Reg. 11415 (August 30, 1966).

Subsequent amendments to the FDA regulations also shed light on the interpretation of the 1962 regulations applicable to changes in drug labeling. *Grove City College v. Bell*, 465 *U.S.* 555, 567-569, 104 *S.Ct.* 1211, 1218-1219 (1984). In January, 1965, the Commissioner of the FDA proposed changes in the regulations regarding supplemental information for both pending new drug applications and supplemental applications. The preamble of the proposed amendments stated the following:

> The Commissioner of Food and Drugs has concluded that in the interest of drug safety certain kinds of changes in the labeling and manufacturing of new drugs, proposed in supplemental new drug applications, should be placed into effect at the earliest possible time. Accordingly, the new-drug regulations (21 C.F.R. 130.4, 130.9) are amended, as hereinafter indicated, to enable prompt adoption of such changes. [30 Fed. Reg. 993 (January 30, 1965)].

Because this case involves a change in labeling subsequent to the approval of the new drug application for Declomycin, the amendment to C.F.R. §130.9 is relevant to this inquiry. In that respect, subparagraph (d) was added in 1965 to the 1960 version of C.F.R. §130.9. It provided that labeling changes containing "additional warning, contraindication, side-effect, and precaution information" may be placed in the product labeling and promotional literature "at the earliest possible time. . . ." §130.9(d)(1). C.F.R. §130.9(e) was also added. It provided assurance to the manufacturer that the FDA would "take no action against a drug or applicant solely because changes of the kinds described in paragraph (d) of this section are placed in effect by the applicant prior to his receipt of a written

notice of approval of a supplemental new-drug application. . . ." *Id.* However, even under the 1965 amendments, "once FDA has acted on the supplement - for example, by rejecting it - the manufacturer has no freedom to alter the package insert by adding information different from or in addition to what FDA has approved." Cooper, *Drug Labeling and Products Liability: The Role of the Food and Drug Administration*, 41 Food, Drug Cosm. L.J. 233, 235 (1986).[11]

In 1966, the process of mandatory prior approval for antibiotics was also slightly modified in that changes in mailing and promotional pieces were exempted from prior approval but only if certified by the manufacturer as "essentially" the same as the labeling previously approved by the FDA. 21 C.F.R. §146.2 (1967), 31 Fed. Reg. 11415 (Aug. 30, 1966). In connection with that change, Commissioner Goddard stated:

> Heretofore, the regulations have required specific advanced approval of each mailing piece. Upon this order becoming effective, initial promotional labeling must be approved before use, but subsequent mailing and promotional pieces certified by the applicant (or authorized representative) to be essentially the same as the approved labeling, need not be given prior approval. [31 Fed. Reg. 11415 (August 30, 1966)].

Except for that change, however, the FDA approval procedures for changes in antibiotic labeling, unlike those for prescription drugs, remained intact. Ultimately, the FDA began regulating antibiotics like most other prescription drugs and authorized labeling changes for them without

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[11] Thus, under the facts in this case, even if the 1965 regulations were in effect in 1962 and Lederle could have warned without advance approval, FDA's rejection of Lederle's proposal would have required Lederle to rescind the warning, at least as to Declomycin. See also, *Hurley*, 863 *F.2d* at 1179 on this point.

advanced approval in those limited circumstances permitted for other prescription drugs. As the FDA noted, however, until those changes were made all antibiotic labeling changes (except those advertising changes previously referred to) "require[d] FDA approval of the change[s] before [they could] be made." 47 Fed. Reg. 46635 (October 19, 1982).

Clearly, a proposed warning that Declomycin causes tooth staining when administered in the developmental process of tooth formation constitutes "a material change" in the labeling of the product. Under C.F.R. §130.9(a) (1960), Lederle faced a suspension of its new drug application if the drug was marketed with the new labeling "before a supplement [was] effective for such change," if the labeling "contain[ed] an untrue statement of a material fact." Lederle petitioned the FDA in November, 1962, for permission to add an appropriate warning to the labeling for "all oral and parenteral tetracycline and chlortetracycline products. . . ." It is clear from the FDA correspondence of February 18, 1963 and April 12, 1963 addressed to Lederle that the FDA did not believe Lederle's suggested warning change was a true statement, at least as to Declomycin, because it specifically excluded Declomycin from the warning requirement. Although plaintiff's counsel argued in his summation to the jury that Lederle lobbied the FDA for that exclusion, there is no evidence in the record to support such an inference. It is clear that the FDA's letter of February 18, 1963 to Lederle was in direct response to Dr. Swanzey's inquiry of February 14, 1963, which on its face was only a request for clarification from the FDA. Dr. Swanzey's letter to the FDA requesting clarification of the FDA's position simply stated: "I assume that this statement is being proposed for chlortetracycline, oxytetracycline and demethylchlortetracycline as well." Indeed, the labeling ultimately suggested by the FDA in its letter of April 12, 1963 to Lederle specifically excluded the generic term

"tetracycline" from the warning and provided a blank space in the body of the warning so that each manufacturer could substitute the brand name of the product for which a warning was required.[12] Moreover, the FDA's press release to medical and dental journals, dated April 18, 1963, specifically excluded Declomycin from the warning when it said in part: "[t]here is no evidence to date that a fourth drug, demethylchlortetracycline, causes the discoloration, FDA said."

Plaintiff argues that "FDA interpretation of the FDCA for twenty-two years has officially sanctioned placement of warnings without its prior approval [30 Fed. Reg. §993-994 (1965)]; . . . ." We agree with plaintiff's statement as far as it goes, but it is irrelevant in the context of this case. Notably, the federal regulation relied upon by plaintiff in making the statement is the 1965 amendment which substantially changed the wording of the applicable 1962 regulation. The focus must appropriately be on FDA's requirements in 1962 when Lederle acted upon its acquired knowledge, not the FDA's amended regulations in 1965.

Plaintiff does not challenge Lederle's or *amici's* interpretation of the FDA regulations in force in 1962. Rather, plaintiff relies upon the brief reference in *Feldman I* to

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[12] The proposed warning contained in the FDA letter of April 12, 1963 addressed to Dr. Swanzey of Lederle Laboratories was as follows: "(name of product) may form a stable calcium complex in any bone forming tissue with no serious harmful effects reported thus far in humans. However, use of (name of product) during tooth development (= last trimester of pregnancy, neonatal period and early childhood) may cause discoloration of the teeth (= yellow-grey-brownish). The effect occurs mostly during long-term use of the drug but it has also been observed in usual short treatment courses". In contrast the warning proposed by Lederle on November 16, 1962 read as follows: "During therapy tetracycline may form a stable calcium complex in bone-forming tissue with no known harmful effects. Use of any tetracycline during tooth development in the neonatal period or early childhood may cause discoloration of the teeth."

21 C.F.R. 130.9., 25 Fed. Reg. 12,595 (1960) and the Court's statement: "We note that the regulation did not prevent a drug manufacturer from adding an additional warning as soon as it was aware of its necessity." *Feldman*, 97 *N.J.* at 459. We do not know the context in which that regulation was placed before the Supreme Court. The passage from the regulation quoted by the Court was taken from paragraph (b) of C.F.R. §130.9 (1960). We are constrained to observe that paragraph (b) addresses the procedure to be followed when the manufacturer proposes changes in "labeling,. . .that are *not significant from the standpoint of the safety* of the new drug as established by the original new-drug application." (emphasis added). C.F.R. §130.9(b) (1960).

In the context of the material contained in the record before us, we conclude that C.F.R. §130.9(b) (1960) was inapplicable to the change in labeling proposed by Lederle in November, 1962. Lederle's proposal was clearly a significant departure from its prior labeling of all its tetracycline products and impacted greatly on safety. Under the circumstances, C.F.R. §130.9(a) (1960) was the applicable regulation. It provided in part:

> A supplemental application should be submitted for any change . . . that may alter the conditions of use, the labeling, the safety, . . . or purity of the drug. . . . Labeling changes includes deviations from the authorized brochure in any mailing or promotional piece used after the drug is on the market. . . . If a material change is made in the . . . labeling or advertising, from the representations in an effective application for a new drug, and the drug is marketed before a supplement is effective for such change, the application may be suspended under §130.27 on the grounds that it contains an untrue statement of a material fact. [C.F.R. §130.9(a) (1960)].

We believe that the clear wording of this paragraph required Lederle to seek the approval of the FDA to change the package inserts dispensed with the drug, including any "mailing" or "promotional piece[s]" or suffer suspension of its "effective" new drug application. In addition, the FDA's correspondence with Lederle, the 1965 amendments to §130.9, and the statements by the Commissioner concerning the purpose of the later amendments, are extrinsic aids in support of our interpretation of the regulations applicable to Lederle in 1962. An administrative agency's interpretation of its own regulations is controlling "unless it is plainly erroneous or inconsistent with the regulation." *Udal v. Tallyman*, 380 U.S. 1, 16-17, 85 *S.Ct.* 792, 801 (1965); *Ford Motor Credit Co. v. Milhollin*, 444 *U.S.* 555, 566, 100 *S.Ct.* 790, 797 (1980); *In re Appeal of Lembo*, 151 *N.J. Super.* 242, 249 (App.Div. 1977). Plaintiff has not argued that the FDA's refusal to allow Lederle to change the warning was conduct inconsistent with its regulatory authority. Indeed, we find that the FDA's conduct comported in all respects with the wording of the regulations.

Only two cases have been located which specifically interpret the 1960 version of C.F.R. §130.9(a). *Roginsky v. Richardson-Merrell, Inc.*,, 378 *F.2d* 832, 835, 848 (2nd Cir. 1967) and *Miller v. Upjohn Co.*, 465 *So. 2d* 42, 45 (Ct.App.La. 1985), *cert. denied* 467 *So. 2d* 533 (1985). Both cases interpreted the regulation applicable at that time to require prior approval from the FDA before a labeling change could be made.[13]

Plaintiff argues that cases are legion that hold compliance with FDA labeling requirements is insufficient to pre-

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[13] *Sterling Drug, Inc. v. Cornish*, 370 *F.2d* 82 (8th Cir. 1967) is an inadequate warning case involving the drug Aralen consumed by plaintiff between November, 1958 and December, 1962. The opinion assumed, as a given, Sterling's obligation to obtain FDA's prior approval for labeling changes but premised liability on Sterling's failure to act promptly in securing it.

clude tort liability against drug manufacturers. Plaintiff cites a statement made by the FDA Commissioner in 1978 that "the boundaries of civil tort liability for failure to warn are controlled by applicable State law." *MacDonald v. Ortho Pharmaceutical Corp.*, 475 *N.E.2d* 65, 70 (S.Ct. Mass. 1985), *cert. den.*, 474 *U.S.* 920, 106 *S.Ct.* 250 (1985) (Referring to the preamble to the 1978 FDA regulations. 433 Fed. Reg. 4214. January 31, 1978); see also, *Odgers v. Ortho Pharmaceutical Corp.*, 609 *F.Supp.* 867, 877 (D.Mich. 1985); *McEwen v. Ortho Pharmaceutical Corp.*, 528 *P.2d* 522, 533-535 (Or. 1974). However, the Commissioner's statement was made in the context of the existing FDA regulation which, at that time, did not require prior approval of labeling changes. (Specifically, *MacDonald*, *Odgers* and *McEwen* involve birth control pills and address the issue of whether the drug warnings approved by the FDA must be given to the consumer as well as the prescribing physician under state law, and, if so, whether there is anything in the FDA regulations which would preclude a state imposed duty to do so.)

Plaintiff also relies upon cases where the drug manufacturer used FDA approval of the wording of the warning as a defense to the plaintiffs' claim in those cases that the warnings were inadequate. *Ezagui v. Dow Chemical Corp.*, 598 *F.2d* 727 (2d. Cir. 1979); *Osburn v. Anchor Laboratories*, 825 *F.2d* 908 (5th Cir. 1987) *cert. den.*, — *U.S.* 108, *S.Ct.* 1476 (1988). To the extent that such cases suggest that the defendants therein failed to give the FDA information which they had in their possession and such failure contributed to the inadequacy of the warning, they simply recognize the "passive" role of the FDA described earlier in *Hurley*. 863 *F.2d* at 1179. An FDA approved warning is only as good as the information provided to it by the manufacturer.[14] If the information is withheld by

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[14] It was in this context that one court had occasion to observe that FDA regulations are "minimal" standards. *Stromsodt v. Parke - Davis*

the manufacturer, we agree with the *Hurley* court that liability can exist notwithstanding FDA approval of the warning. *Id.* However, the facts do not support such a claim in this case and plaintiff does not contend that they do.

*Osburn* and *Hurley* were decided by the 5th Circuit Court of Appeals. *Hurley*, the more recent of the two opinions, agreed with *Osburn's* view that FDA regulation of the drug field is not so pervasive that a general, implied preemption claim can be sustained. The court said: "FDA regulation does not preempt the types of state law duties which are the basis of the plaintiffs' claims: the duty to warn of product risks, *e.g. Osburn v. Anchor Laboratories, Inc.*, 825 *F.2d* 908, 911-912 (5th Cir. 1987). . . ." *Hurley*, 863 *F.2d* at 1177. Yet the court held that there can be narrow preemption of an issue in certain warning cases depending upon the facts. *Id.* at 1179. Obviously, the *Hurley* court saw no conflict between its decision and those cases decided in the same vein as *Osburn*, which stand only for the proposition that general implied preemption by the FDA is not warranted.

*Toner for Toner v. Lederle Laboratories*, 779 *F.2d* 1429 *cert. den.* ___ U.S. ___, 108 *S.Ct.* 1122 (1988), (9th Cir. 1986), also relied upon by plaintiff, does not fit neatly into the class of cases exemplified by *Osburn* and *Ezagui*, but it is analogous. In that case, plaintiff's theory of liability was that Lederle should have developed a fractionated cell vaccine rather than the whole cell vaccine which it submitted to the FDA for license approval. The question presented was one of the adequacy of Lederle's research. The

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*and Company*, 257 *F.Supp.* 991, 997 (D.N.D. 1966), aff'd 411 *F.2d* 1390 (8th Cir. 1969). The crux of the trial judge's findings of fact was that defendant had obtained FDA approval prematurely based on inadequate testing, and, thus, the FDA's approval was no better than the information on which it was based. See also, *Brochu v. Ortho Pharmaceutical Corp.*, 642 *F.2d* 652 (1st Cir. 1981).

opinion in the case is far from definitive on the question of preemption because of the Circuit Court's uncertainty of Idaho substantive law. At best, it inferentially recognizes the passive role of the FDA in the licensing scheme and, read liberally in favor of plaintiff, simply holds that Lederle could not rely on the FDA's approval of a whole cell vaccine and the FDA's refusal to relicense a fractionated cell vaccine as a defense to plaintiff's claim that proper research and development would have proven the efficacy of the latter over the former.

While these cases differ from the present case on the facts and plaintiffs' theory of recovery, we agree with plaintiff's general premise here that the great weight of authority holds that state tort law imposing liability for failure to adequately warn about known adverse reactions of prescription drugs is not impliedly preempted by the FDCA or FDA regulations pursuant thereto. We add to those cases previously cited: *O'Gilvie v. International Playtex, Inc.*, 821 *F.2d* 1438 (10th Cir. 1987) *cert. den.* ___ U.S. ___, 108 *S.Ct.* 2014 (1988); *Brochu v. Ortho Pharmaceutical Corp.*, 642 *F.2d* 652 (1st Cir. 1981); *Salmon v. Park David and Company*, 520 *F.2d* 1359 (4th Cir. 1975). However, as stated earlier, our decision here is not based on implied preemption, but rather on conflict preemption and is limited to a holding that the specific issue decided by the jury imposing liability on Lederle was preempted as a result of direct conflict between our State's decisional law and the FDA's regulations in 1962.

We adopt the reasoning of the *Hurley* court. Applying that reasoning to the present case, we conclude that plaintiff's state tort claim was not preempted to the extent that plaintiff sought damages based on Lederle's alleged awareness of Declomycin's side effects earlier than Lederle admitted to have gained such knowledge. That theory of recovery did not conflict with federal law. Indeed, federal regulations and New Jersey decisional law in that respect compliment each other. FDA regulations require manufac-

turers to file annual reports as well as immediate reports of all unexpected adverse reactions. 21 C.F.R. §130.35(e) and (f). Clearly, New Jersey decisional law also requires prompt response to knowledge of adverse reactions. *Feldman*, 97 *N.J.* at 456. Federal regulations which compliment state tort law may actually serve to establish a standard of care to which state law may refer. See, *Stanton by Brooks v. Astra Pharmaceutical Products*, 718 *F.2d* 553, 563-565 (3rd Cir. 1983). However, as stated earlier, the jury's verdict in this case rejected plaintiff's argument on that theory when it found Lederle's product was not defective for lack of warning in 1960 and 1961. The jury found that Lederle's product was defective in 1962 and 1963, but, as indicated earlier in this opinion the only basis for that finding was its belief that Lederle should have warned in 1962 when it admittedly became aware of the causal relationship between the ingestion of tetracyclines and tooth staining without first seeking the FDA's approval. To the extent that the jury found that Lederle should have warned in 1962 and 1963 based on the trial judge's instruction that prior approval from the FDA was not required, State law is in direct conflict with federal law applicable at that time and must yield. As the U.S. Supreme Court said in *Southern Railway Co. v. Reid*, *supra*, there can be no "middle ground" where such a conflict exists and the state law on that point "must be silent." 222 *U.S.* at 442, 32 *S.Ct.* at 144.

In *Feldman I* the Supreme Court expressed concern that a decision interpreting federal regulations to preclude drug manufacturers from warning about side effects without first obtaining FDA approval would appear "anomalous." *Feldman*, 97 *N.J.* at 459. That is so because heretofore in New Jersey, at least as to consumer goods, warnings of possible dangers were considered to have appreciable negative impact on the utility of the product. For that reason it has been said that where warnings are an issue, the risk-utility analysis is irrelevant and a warning should

always be given. *Freund v. Cellofilm Properties, Inc.*, 87 *N.J.* 229, 242 (1981); *Beshada v. Johns-Manville Products Corp.*, 90 *N.J.* 191, 201-202 (1982). Thus, if federal law were to mirror State law one might assume that a federal agency would require a drug manufacturer to warn as soon as it learns of the adverse effect of the drug.

However, the United States Supreme Court has recognized that in approving a new drug the FDA must balance the "expected therapeutic gains" against the "risks entailed by its use." *United States v. Rutherford*, 442 *U.S.* 544, 555, 99 *S.Ct.* 2470, 2477 (1979). The FDA draws from a broad range of expertise in seeking to decide the "[u]tilitarian questions regarding 'how safe' or 'how effective' a given drug must be to justify its usage or marketability." *Note, The Drug Amendments of 1962: How Much Regulations?*, 18 Rutgers L.Rev. 101, 156 (1963). There is no question that risk-utility determinations govern virtually every stage in the development and approval of a new drug. See, *Chien, Issues in Pharmaceutical Economics*, (1979). The concept of risk-utility carries over to the labeling process. As the FDA has noted:

> Labeling is not intended to be a dispositive treatise of all possible data and information about a drug. It is intended instead to advise about potential hazards and to convey documented statements concerning safety and effectiveness. The Act permits labeling statements with respect to safety only if they are supported by scientific evidence.
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> . . .
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> The Commissioner concludes that drug labeling should include a contraindication only when reasonable evidence exists indicating an association between the drug and a hazard. The Commissioner believes that including theoretical hazards as contraindications in drug labeling would cause

> that very important section of the labeling to lose its significance. [44 Fed. Reg. 37441, 37447 (June 26, 1979)].

Moreover, the FDA has stated:

> It is . . . apparent that there are very few statements in prescription drug labeling on which some controversy could not be found within the medical profession. Not infrequently, there are several points of view on a single issue. To permit or require statements of conflicting opinion on all of these matters would destroy the present usefulness of prescription drug labeling. [39 Fed. Reg. 33232 (Sept. 16, 1974)].

With specific reference to the 1962 amendments, the FDA observed:

> Under the 1962 amendments . . . the Food and Drug Administration is required to review the labeling for every new drug, including the package insert for prescription new drugs, and to approve it as not false or misleading in any particular. In approving the labeling the Food and Drug Administration must determine both that the content is entirely truthful, and that it omits no information pertinent to the safe and effective prescribing of the drug by the physician. . . . *As the law now stands, therefore, the Food and Drug Administration is charged with the responsibility for judging the safety and effectiveness of drugs and the truthfulness of their labeling.* [37 Fed. Reg. 16503 (August 15, 1972) (emphasis added)].

Thus, the FDA's interest in risk balancing goes beyond the issue of whether a drug should be marketed. The FDA is interested in "rational prescribing," i.e., insuring that the risks and benefits of a particular drug be fairly presented so that a physician can compare them with other

available therapies. That goal "is not advanced if a drug is made to appear riskier than other drugs and other therapies due to the over-dramatization of risk information or the presentation of risk information that should not rationally influence prescribing (or treatment) decisions." Cooper, *supra*, 41 Food Drug Cosm. L.J. 233, 238. This concept has been judicially recognized.

> The quality of evidence supporting a casual connection between product and injury may change from extremely vague to highly certain. . . . [I]f every report of a possible risk, no matter how speculative, conjectural, or tentative, imposed an affirmative duty to give some warning, a manufacturer would be required to inundate physicians indiscriminately with notice of any and every hint of danger, thereby inevitably diluting the force of any specific warning given. [*Finn V. G. D. Searle & Co.*, 677 *P. 2d.* 1147, 1153 (Cal. 1984). See also, *Sterling Drug, Inc. v. Yarrow*, 408 *F.2d.* 978, 991-992 (8th Cir. 1969)].

The utility of Declomycin as an antibiotic has never been seriously questioned. Indeed, Dr. Harold Feldman, plaintiff's father, and Dr. Shwachman, plaintiff's expert witness, so testified. See, *United States v. An Article of Drug, Etc.*, 394 *U.S.* 784, 89 *S.Ct.* 1410 (1969). Thus, in reviewing Lederle's November, 1962 request to change the labeling of its tetracycline drugs in order to warn of possible tooth discoloration, the FDA had to balance the substantial therapeutic benefits that these drugs had in the treatment of a wide range of infections against the scientifically knowable risks of tooth staining in normal healthy children. Dr. Barzilai of the FDA, in his December 2, 1962 letter replying to Lederle's proposal, advised Lederle that the issue had to be reviewed from a "medical, scientific [and] regulatory" point of view. In his own way, Dr. Barzilai was advising Lederle that the FDA had to consider the impact such a warning would have on "ra-

tional prescribing" if Lederle's suspicions about the side effects proved unfounded.

The "anomaly" exists only if we are compelled to impose current New Jersey decisional law, which ostensibly requires the manufacturer to warn as soon as it learns of the side effects, upon the FDA's judgment in 1962 as to how best to implement the risk-utility analysis necessary for rational prescribing. It is tempting to hold that because the FDA now permits a drug manufacturer to warn without prior approval, thereby placing FDA regulations in harmony with current New Jersey law, Lederle had a duty to warn without waiting for FDA approval. Assuming that our interpretation of the FDA regulations applicable in 1962 is correct, there are two reasons why that cannot be done: one reason is found in State law and the second in federal law. Under New Jersey strict liability law the product's defect must be proven as of the time of marketing not at the time of trial. *Feldman*, 97 *N.J.* at 452. Indeed, this concept was made explicit when the Supreme Court distinguished *Feldman I* from *Beshada v. Johns-Manville Products Corp.*, 90 *N.J.* 191 (1982) and limited *Beshada's* future application to "the circumstances giving rise to its holding." *Id.* at 455. *Beshada* had applied a time of trial test in determining whether a defect existed. See Wade, *On the Effect in Product Liability of Knowledge Unavailable Prior to Marketing*, 58 N.Y.U.L. Rev. 734, 763 (1983). Thus, only the regulations applicable at the time of marketing are relevant. Further, since *Feldman I* was decided, our Supreme Court has recognized both the risk-benefit analysis of the FDA regulatory scheme and the FDA's policy with regard to how warnings are most effectively communicated. Relying at least in part on that analysis, the Court concluded that a drug company had no tort duty to directly warn the patient of side effects resulting from the administration of DPT vaccine. *Niemiera by Niemiera v. Schneider*, 114 *N.J.* 550, 560 (at footnote 3), 562 (1989).

Under Federal Law, it is not appropriate for a court using hindsight to say that the FDA's implementation of the FDCA was unwise in the years 1962-1963. Where the FDA's interpretation of the FDCA or its regulations is "sufficiently rational," it must be given deference and such a finding "preclude[s] a court from substituting its judgment for that of the FDA." *Young v. Community Nutrition Institute*, 476 *U.S.* 974, 981, 106 *S.Ct.* 2360, 2365 (1986).

Reversed and remanded for the entry of an order of judgment in favor of the defendant.

## STATUTES INVOLVED

Between 1959 and 1963, the Federal Food, Drug and Cosmetic Act, 21 *U.S.C.* §301, provided:

**§ 321. Definitions; Generally**

For the purposes of this Chapter -

* * *

(m) The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

* * *

**§ 331. Prohibited Acts**

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded.

* * *

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

* * *

**§ 333. Penalties—Violation of Section 331 of This Title**

(a) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

* * *

**§ 352. Misbranded Drugs and Devices**

A drug or device shall be deemed to be misbranded --

* * *

(1) If it is, or purports to be, or is represented as a drug, composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, *or any other antibiotic drug*,[1] or any derivative thereof, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 357 of this title, and (2) such certificate or release is in effect with respect to such drug:

* * *

**§ 357. Certification of Drugs Containing penicillin, streptomycin, chlortetracycline, chloramphenicol or bacitracin—Regulations prescribed by Secretary; release prior to Certification; "antibiotic drug" defined**

(a) The Secretary of Health, Education and Welfare,[2] pursuant to other regulations promulgated by him, shall provide for the certification of batches of drugs composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof. A batch of any such drug shall be certified if such drug has such characteristics of identity and such batch has such characteristics of strength, quality, and purity, as the Secretary prescribes in such

---

[1] Added by Pub. L. 87-781, § 105(c) (1962).

[2] The Secretary of Health, Education and Welfare was redesignated the Secretary of Health and Human Services in any law in force on the effective date of Pub. L. 96-88. *See* Pub. L. 96-88 §601, 93 *Stat.* 696 (1979).

regulations as necessary to adequately insure safety and efficacy of use, but shall not otherwise be certified. Prior to the effective date of such regulations, the Secretary, in lieu of certification, shall issue a release for any batch which, in his judgment, may be released without risk as to the safety and efficacy of its use. Such release shall prescribe the date of its expiration and other conditions under which it shall cease to be effective as to such batch and as to portions thereof. *For purposes of this section and of section 352(1) of this title, the term "antibiotic drug" means any drug intended for use by man containing any quantity of any chemical substance which is produced by a microorganism and which has the capacity to inhibit or destroy microorganisms in dilute solution (including the chemically synthesized equivalent of any such substance).*[3]

**PROVISIONS OF REGULATIONS**

(b) Regulations providing for such certifications shall contain such provisions as are necessary to carry out the purpose of this section, including provisions prescribing (1) standards of identity and of strength, quality, and purity; (2) tests and methods of assay to determine compliance with such standards; (3) effective periods for certificates and other conditions under which they shall cease to be effective as to certified batches and as to portions thereof; (4) administration and procedure; and (5) such fees, specified in such regulations, as are necessary to provide, equip, and maintain an adequate certification service. Such regulations shall prescribe only such tests and methods of assay as will provide for certification or rejection within the shortest time consistent with the purposes of this section.

---

[3] Added by Pub. L. 87-781, § 105(a) and (b) (1962).

* * *

**§ 371. Regulations and hearings—Authority to promulgate regulations**

(a) The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section is vested in the Secretary.

* * *

The Drug Amendments of 1962, Pub. L. 87-781, 76 *Stat.* 780 (1962), provided:

**EFFECT ON STATE LAW**

Sec. 202. Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provisions of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law.

**REGULATIONS INVOLVED**

In 1962 and 1963, Subchapter C (Drugs) of Chapter 1 (Food and Drug Administration) of Title 21 of the Code of Federal Regulations (1963), promulgated pursuant to the authority vested in the Secretary of Health, Education and Welfare by the Federal Food, Drug and Cosmetic Act (21 *U.S.C.* §§ 355, 357, 371) and delegated to the Commissioner of Food and Drugs by the Secretary. 20 *Fed. Reg.* 1966 ( ); 22 *Fed. Reg.* 1045 ( ), provided:

## PART 130 - NEW DRUGS[4]

### § 130.4 Applications.

(c) Applications shall be submitted in the following form:

* * *

(8) If this is a supplemental application, full information on each proposed change concerning any statement made in the effective application.

(After an application is effective a supplemental application may propose changes. The supplemental application may omit statements made in the effective application concerning which no change is proposed. A supplemental application should be submitted for any change beyond the variations provided for in the application that may alter the conditions of use, the labeling, the safety, identity, strength, quality or purity of the drug or the adequacy of manufacturing methods, facilities or controls to preserve them. When necessary for the safety of the drug, a supplemental application may be required to specify a period of time within which the proposed change will be made; and in such case the distribution of the drug after such time without such change constitutes distribution without an effective new-drug application. A supplemental application is not required when the article is no longer a new drug unless the proposed change itself causes it to become a new

---

[4] The FDA regulations in Part 130 governed "new drug applications" approved pursuant to 21 U.S.C. § 355. They were incorporated by reference in the regulations governing the labeling of antibiotics certified pursuant to 21 U.S.C. § 357. *See* 21 C.F.R. § 146.1(g) (1963) and the 1957 amendments to 21 C.F.R. §§ 146.3(a)(1) and (2) and 146.4(a)(3) and (b)(2), which changed the words "of this part" in the antibiotic regulations to read "of this chapter." *See* 22 *Fed. Reg.* 8118 (Oct. 12, 1957).

drug. If a material change is made from the representations in an effective application for a new drug before a supplement is effective for such change, the application may be suspended under § 130.27.)

(9) It is understood that the labeling and advertising for the drug will prescribe, recommend, or suggest its use only under the conditions stated in the labeling which part of this application; and if the article is a prescription drug, it is understood that any labeling which furnishes or purports to furnish information for use or which prescribes, recommends, or suggests a dosage for use of the drug will also contain substantially the same information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, any relevant hazards, contraindications, side effects, and precautions, contained in the labeling which is part of this application. It is understood that all representations in this application regarding the components, composition, manufacturing methods, facilities, controls, and labeling apply to the drug produced until an effective supplement to the application provides for a change or the applicant is notified in writing by the Food and Drug Administration that a supplemental application is not required for the change, or the article is no longer a new drug. It is further understood that a new drug for which an application is conditionally effective may not be marketed until the stated conditions have been met, including when such is a condition, the submission of final printed labeling identical in content to the draft copy of the application, and including, when such is a condition, a notification by the New Drug Branch that an inspection has verified the adequacy of the manufacturing methods, facilities, and controls described in the application.

* * *

**§ 130.9 Supplemental Applications.**

(a) After an application is effective, a supplemental application may propose changes. The supplemental application may omit statements made in the effective application concerning which no change is proposed. A supplemental application should be submitted for any change beyond the variations provided for in the application (including changes in the scale of production such as from pilot-plant to production batch), that may alter the conditions of use, the labeling, the safety, identity, strength, quality or purity of the drug or the adequacy of manufacturing methods, facilities, or controls, to preserve them. Labeling changes include deviations from the authorized brochure in any mailing or promotional piece used after the drug is placed on the market. When necessary for the safety of the drug, a supplemental application may be required to specify a period of time within which the proposed change will be made; and in such case the distribution of the drug after such time without such change constitutes distribution without an effective new-drug application. If a material change is made in the components, composition, manufacturing, methods, facilities, or controls, the labeling or advertising from the representations of an effective application for a new drug, and the drug is marketed before a supplement is effective for such change, the application may be suspended under § 130.27 on the grounds that it contains an untrue statement of material fact.

(b) The submission of a supplemental new drug application is not required for changes made in the new drug, or in its labeling, or in the manufacturing facilities or controls underwhich it is produced, that are not significant from the standpoint of the safety of the new drug as established by the original new-drug application. The holder of an effective new drug application should submit to the New Drug Branch, in writing, full details of any proposed change or changes, and he will be no-

tified in writing whether, in the Food and Drug Administration's opinion, the submission of a supplemental application is required for such change or changes. This includes all mailing and promotional pieces that are to be used after the new drug has been placed on the market.

**PART 146 - GENERAL REGULATIONS FOR THE CERTIFICATION OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS**

**§ 146.2 Requests for Working Standards and Certification; Information and Samples Required.**

* * *

(b) The initial request for certification of a batch of any drug submitted by any person shall be preceded or accompanied by a full statement of the facilities and controls used to maintain the identity, strength, quality, and purity of each batch, including a description of (1) the methods and processes used in the manufacture of the drug; (2) the tests and assays of the drug made during the manufacture of the batch and after it is packaged; and (3) the laboratory facilities used in such controls. Such initial request shall also be preceded or accompanied by the key of the batch marks used by such person and by specimens of all labeling (including specimens of all brochures and other printed matter except readily available medical publications, referred to in such labeling) to be used for such drug. When any change is made in any such facility, or control, or in any such key or labeling, such person shall promptly submit to the Commissioner a full statement of such change or, in the case of changed labeling, specimens showing all such changes.

* * *

**§ 146.3 Certification.**

(a) If it appears to the Commissioner, after such investigation as he considers necessary, that:

(1) The information (including results of tests and assays) and samples required by or pursuant to the regulations in this chapter have been submitted, and the request for certification contains no untrue statement of a material fact; and

(2) the batch complies with the regulations in this chapter and conforms to the applicable standards of identity, strength, quality, and purity prescribed by the regulations in this chapter;

the Commissioner shall certify that such batch is safe and efficacious for use subject to such conditions on the effectiveness of certificates as are prescribed by § 146.4, shall issue to the person who requested it a certificate to that effect.

* * *

**§ 146.4 Conditions on the Effectiveness of Certificates.**

(a) A certificate shall not become effective:

* * *

(3) With respect to any package unless its label and labeling bear all words, statements, and other information required by the regulations in this chapter;

(b) A certificate shall cease to be effective:

* * *

(2) With respect to any immediate container when it or its seal (if the regulations in this part require it to be sealed) is broken, or when its label or labeling is altered, mutilated, destroyed, obliterated, or removed in whole or in part, or ceases to conform to any labeling

requirement prescribed by the regulations in this chapter, except that

(i) If the drug in such container is repacked or used as an ingredient in the manufacture of another drug, and certification of the batch thus made is requested, such certificate shall continue to be effective for a reasonable time to permit certification or destruction of such batch;

(ii) If the drug is in a container packaged for dispensing and is used in compounding a prescription issued by a practitioner licensed by law to administer such drug, such certificate shall continue to be effective for a reasonable time to permit the delivery of the drug compounded on such prescription; or

(iii) If its label or labeling is removed in whole or in part for the purpose of relabeling and supplemental certification of the relabeled drug is requested, as provided by § 146.18.

* * *

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No. 91-685

In The

# Supreme Court of the United States

October Term, 1991

LEDERLE LABORATORIES, Division Of American Cyanamid Company,

*Petitioner,*

v.

CAROL ANN FELDMAN,

*Respondent.*

## Petition For A Writ Of Certiorari To The Supreme Court Of New Jersey

## BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

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## QUESTION PRESENTED

Whether procedural United States Food and Drug Administration regulations, lacking either express or implied preemptive effect, supersede imposition of tort liability under state common law when compliance with both federal and local requirements was by no means impossible.

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## STATEMENT OF THE CASE

The facts are stated fully in the decisions of the New Jersey Supreme Court, 97 *N.J.* 429, 436-440, 479 *A.2d* 374, 377-380 (1984) ("Feldman I") and 125 *N.J.* 117, 122-129, 592 *A.2d* 1176, 1178-1182 (1991) ("Feldman II").

## SUMMARY OF ARGUMENT

According to petitioner, certain procedural FDA regulations in place during 1962 and 1963 preempted a state common-law tort action for damages resulting from drug-induced injury. Review of those rules, however, discloses that they neither possess express or implied preemptive effect nor engender irremediable conflict with local claims for compensation. The decision of the New Jersey Supreme Court, according the regulations no preemptive sweep and reinstating an award of damages against petitioner, heeds the approach taken by this Court in the area of federal preemption. Therefore, respondent respectfully requests that this Court deny the petition for a writ of certiorari for want of the "special and important reasons" required by Sup. Ct. R. 10.1.

## REASONS FOR DENYING THE PETITION

### I. THE DECISION OF THE NEW JERSEY SUPREME COURT IS IN HARMONY WITH CONTROLLING INTERPRETATIONS OF THE SUPREMACY CLAUSE.

Both theory and the precedents of this Court teach solicitude for state interests. *United States v. Yazell*, 382

*U.S.* 341, 352 (1966). Deference is commonly accorded general state laws of a particular type – those "that protect interests 'deeply rooted in local feeling and responsibility.'" *New York Telephone Co. v. New York State Dept. of Labor*, 440 *U.S.* 519, 540 (1970) (plurality opinion), quoting *San Diego Building Trade Council v. Garmon*, 359 *U.S.* 236, 244 (1959). Hence, there is a presumption against finding pre-emption of state law in areas traditionally regulated by the States. *California v. ARC America Corp.*, 409 *U.S.* 93, 101 (1989), citing *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 *U.S.* 707, 716[-717] (1985). This specific presumption against preempting exercise by a State of its traditional police powers is especially strong regarding laws that protect the health and safety of its citizens. Such laws are those this Court has been most reluctant to invalidate. Note, "A Framework for Preemption Analysis", 88 Yale L.J. 363, 374 (1978).

When Congress legislates in a field traditionally occupied by the States, this Court commences review "with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress," *Rice v. Santa Fe Elevator Corp.*, 331 *U.S.* 218, 230 (1947), and places the burden of demonstrating preemption on the party who seeks it. *Silkwood v. Kerr-McGee Corp.*, 464 *U.S.* 238, 255 (1984). Under ordinary circumstances that burden is a formidable one. *Motor and Equipment Manufacturers Ass'n. v. Environmental Protection Agency*, 201 *U.S.App.D.C.* 109, 627 *F.2d* 1095, 1107 n. 20 (D.C.Cir.), *cert.* denied *sub nom. General Motors Corp. v. Costle*, 446 *U.S.* 952 (1980).

The New Jersey Supreme Court, always at the forefront in developing the doctrine of strict liability in tort, remains strongly committed to the proposition that the distributor of a defective product "should compensate its victims for the misfortune that it inflicted on them." *Beshada v. Johns-Manville Products Corp.*, 90 *N.J.* 191, 204, 447 *A.2d* 539, 546 (1982). Because federal food and drug laws serve a complimentary, salutary purpose, see *United States v. Wiesenfeld Warehouse Co.*, 376 *U.S.* 86, 91 (1964), courts have rejected as paradoxical the present preemption arguments. See *Kellogg Co. v. Mattox*, 763 *F.Supp.* 1369, 1379-1381, 1385-1386 (N.D.Tex. 1991). Knowing the purpose of the law to be "the ever insistent consideration in its interpretation", *United States v. Antikamnia Chemical Co.*, 231 *U.S.* 654, 667 (1914), the New Jersey Supreme Court concluded that the provision of tort remedies to compensate for personal injuries "is a subject matter of the kind this Court has traditionally regarded as properly within the scope of state superintendence." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 *U.S.* 132, 144, reh. den., 374 *U.S.* 858 (1963), as quoted in *Ferebee v. Chevron Chemical Co.*, 237 *U.S.App.D.C.* 164, 736 *F.2d* 1529, 1542 (D.C.Cir.), *cert.* denied, 469 *U.S.* 1062 (1984); *P.R. Consumer Affairs Dept. v. Isla Petroleum*, 485 *U.S.* 495, 500-501 (1988). Thus it found "the case for federal preemption . . . a less persuasive one." *New York State Dep't. of Social Services v. Dublino*, 413 *U.S.* 405, 421 (1973). Nor did the court "overlook the body of law relating to the sensitive interrelationship between [laws] adopted by the separate, yet coordinate, federal and state sovereignties", but instead performed a scrupulous analysis "tempered by the conviction that the proper approach is to reconcile

'the operation of both statutory schemes with one another rather than holding one completely ousted.'" *Merrill Lynch, Pierce, Fenner & Smith v. Ware*, 414 *U.S.* 117, 127 (1973).

Congress has not legislatively expressed an intent to preclude States from entering the area of drug regulation. *Pharmaceutical Soc., State of N.Y., Inc. v. Lefkowitz*, 454 *F.Supp.* 1175, 1179 (S.D.N.Y.), aff'd 586 *F.2d* 953 (2nd Cir. 1978), citing *Whalen v. Roe*, 429 *U.S.* 589, 603 n. 30 (1977). Indeed, at no time has the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("the FDCA"), contained pre-emptive language. *Jones v. Rath Packing Co.*, 430 *U.S.* 519, 538 (1977); P.L. 87-781, Title II, § 202, 76 Stat. 793 (October 10, 1962). Whereas federal concern focuses upon the safety and efficacy of prescription drugs, state concern addresses the sale and use of prescription drugs. *Pharmaceutical Soc.*, 454 *F.Supp.* at 1175. A State undoubtedly may regulate the prescription, compounding, purchase, sale, and use of prescription medicines to the extent reasonably necessary to protect public health. *Liggett Co. v. Baldridge*, 278 *U.S.* 105, 111-112 (1928). States are not even barred from regulating product labeling. They are limited only where the labels or warnings pertain to problems which have already been addressed by the federal government, as in *McDermott v. Wisconsin*, 228 *U.S.* 115, 131-132 (1913). *Pharmaceutical Soc.*, 454 *F.Supp.* at 1179, citing *Cosmetic, Toiletry & Fragrance Ass'n. v. State of Minnesota*, 440 *F.Supp.* 1216, 1223 (D.Minn. 1977), aff'd. 575 *F.2d* 1256 (8th Cir. 1978); see also *Feldman* (II), 125 *N.J.* at 143, 592 *A.2d* at 1190.

Neither the FDCA nor its regulations affords injured individuals a private cause of action for damages

consequent to ingestion of injurious pharmaceuticals. Manufacturers that violate its rules are subject through administrative action to injunctions, misdemeanor criminal penalties, and fines. 21 U.S.C. §§ 332, 333. The federal regulatory system, then, serves a deterrent but not a compensatory function. State tort law, on the other hand, compensates aggrieved persons as it prevents future harm. Put another way, rules promulgated by the United States Food and Drug Administration ("the FDA") have only a regulatory aim, while state damage actions have both regulatory and compensatory aims. FDA regulations are therefore not comprehensive; they may be supplemented by the New Jersey common law of duty to warn. *Ferebee*, 736 *F.2d* at 1540.

Examination of the evolution of the FDCA "belies any objective to cloak [it] with preemptive effect." *MacDonald v. Ortho Pharmaceutical Corp.*, 394 *Mass.* 131, 475 *N.E.2d* 65, 70 (Sup. Jud. Ct.), *cert.* den., 474 *U.S.* 920 (1985). The legislative history of the 1938 amendment to the Food and Drugs Act of 1906 clearly shows the intent of Congress to preserve state common-law remedies. The first draft of the 1938 legislation included this provision:

> Liability for Personal Injuries
>
> Sec. 24. A right of action for damages shall accrue to any person for injury or death proximately caused by violation of this Act.

Hearings on S. 1944, Before a Subcomm. of the Comm. of Commerce, 73d Cong., 2d Sess., 10 (1938). This private cause of action was deleted from later drafts after comments that it would duplicate existing rights under state

law. See *State of Florida ex rel. Broward County v. Eli Lilly & Co.*, 329 *F.Supp.* 364, 365 n. 2 (S.D.Fla. 1971).

The legislative history demonstrates a common assumption that state tort law would survive and that a federal cause of action would be duplicative. This explains the virtual silence of Congress on state remedies during discussion of subsequent FDCA amendments. See *e.g.* 108 Cong. Rec. 21083 (September 27, 1962); H.R. Rep. No. 2526, 87th Cong., 2d Sess. (1962).

Respondent freely acknowledges that damage awards under state tort law may regulate conduct. Justice Frankfurter said so in *Garmon*. 359 *U.S.* at 246-247. Pet. 18. Such an admission in no way impairs the logic of the determination under review, however. *Garmon* stands for the proposition that some specific state tort causes of action for damages are preempted by the National Labor Relations Act. 359 *U.S.* at 244. As four concurring Justices made clear, though, the decision rested on a narrow ground, *Id.* at 249, for few state awards of tort compensation consequent to unlawful strike-related activities are preempted pursuant to 29 U.S.C. § 151 *et seq.* Three years later the Court confirmed that fact in *Dowd Box Co. v. Courtney*, wherein it relegated *Garmon* to a footnote. 368 *U.S.* 502, 507-508, and n. 3 (1962).

This case does not revive the dispute whether a state common-law rule permitting imposition of civil liability for failure to provide satisfactory and timely warning of a known harmful quality of a product may be regulatory in effect, which argument arose in *Cipollone v. Liggett Group, Inc.*, 789 *F.2d* 181, 187 n. 6 (3rd Cir. 1986), *cert.* den., 479 *U.S.* 1043 (1987). Here, petitioner is unable to show that

such a regulatory consequence was not "something that Congress was quite willing to accept." See *Silkwood*, 464 *U.S.* at 256, as cited in *Dewey v. R.J. Reynolds Tobacco Co.*, 121 *N.J.*, 69, 89, 577 *A.2d* 1239, 1249 (1990). The majority in *Silkwood* found no inconsistency in letting persons injured by nuclear hazards recover under state tort law, despite Congress' express intent under the Atomic Energy Act of 1954, 42 *U.S.C.* §§ 2011-2284, to have the Nuclear Regulatory Commission exclusively regulate the safety of nuclear facilities. *Feldman* (II), 125 *N.J.* at 150-151, 592 *A.2d* at 1194, citing 464 *U.S.* at 257-258. But see 464 *U.S.* at 263-264 (Blackmun, J., dissenting) and 464 *U.S.* at 276 n. 3 (Powell, J., dissenting) (The indirect effect of compensatory damages awards on manufacturer behavior is not regulatory in nature.).

Petitioner fails to perceive a subtle message from *Garmon*, which held that when an activity arguably is protected by the national Labor Relations Act or is an unfair labor practice under that Act, in accordance with the Act those aggrieved must go to the National Labor Relations Board for relief. State and federal courts are to defer to the Board, even if it has declined to assert jurisdiction. *Garmon*, 359 *U.S.* at 244-245. Thus *Garmon* involved federal regulation by an administrative body which, unlike the FDA at the time Carol Ann Feldman sustained injury, provided its own avenue for redress. Possible preemptive treatment by this Court of state common-law claims must be weighed with that in mind. See *Construction Workers v. Laburnum Corp.*, 347 *U.S.* 656, 663-664 (1954) ("It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.").

The *Silkwood* Court followed *Laburnum*, not *Garmon*. It did so not only because the Atomic Energy Act of 1954, like the FDCA, contains no preemption provision whatever, but also because the language of that Act, like the language of the FDCA, does not indicate that Congress meant to take over the area of compensation to victims of the activity it sought to regulate. *Silkwood*, 464 *U.S.* at 251-252. Compensation under both Acts is left to state court systems wherein, incidentally, the failure to provide adequate warnings of known risks associated with normal use of a drug – violative of 21 *U.S.C.* § 352 – may give rise to a claim of negligence *per se*. *Ezagui v. Dow Chemical Corp.*, 598 *F.2d* 727, 733 (2nd Cir. 1979). "[C]oncern about the uniformity of interpretation, moreover, is considerably mitigated by the fact that . . . this Court retains power to review the decision [under the FDCA] in a state cause of action." *Merrill Dow Pharmaceuticals, Inc. v. Thompson*, 478 *U.S.* 804, 815 (1986).

The New Jersey Supreme Court, in turn, followed *Silkwood*. *Feldman* (II), 125 *N.J.* at 150-151, 592 A.2d at 1194. Perhaps it perceived a pattern evolving in the decisions of this Court, of which *Oneida County, N.Y. v. Oneida Indian Nation*, 470 *U.S.* 239 (1985) is most instructive. There Justice Powell compared the preemptive authority of the Trade and Intercourse Act of 1793 (Nonintercourse Act), 1 Stat. 329, with that of the Federal Water Pollution Control Act as amended (FWPCA), 86 Stat. 816. *Id.* at 236-237. The legislative history of the latter enactment "indicated that Congress intended FWPCA to provide a comprehensive solution to the problem of interstate water pollution." The former "[i]n contrast . . . did not establish a comprehensive remedial plan for dealing with

violations of Indian property rights." The Act which provided no "comprehensive remedial plan" was found to be non-preemptive, while the Act which established "an elaborate system for dealing with the problem of interstate water pollution, providing for enforcement of its terms by agency action and citizens suits," was found to be preemptive. *Id.* at 237.

In *California v. F.E.R.C.*, ___ *U.S.* ___, 110 *S.Ct.* 2024 (1990) the Federal Power Act of 1935, 49 Stat. 803, was held to supersede state laws due, at least in part, to comprehensive procedures established thereunder which afford administrative hearings to those who claim detriment arising from enforcement of its requirements. 110 *S.Ct.* at 2027-2028. The same result obtained in *Chicago & N.W. Transp. v. Kalo Brick & Tile*, 450 *U.S.* 320 (1981) (Pet. 17-18), which dealt with the Interstate Commerce Act as recodified, 92 Stat. 1337 – "among the most pervasive and comprehensive federal regulatory schemes." The Court made a determination that the Act is preemptive of state-court actions against regulated carriers when the Interstate Commerce Commission reaches the merits of the matter which the shipper seeks to raise in state court because the Act "in fact spells out with considerable precision the remedies available to a shipper who is injured" wrongfully. *Id.* at 318, 321-322, 323 n. 10, 331-332; compare *Raymond v. Riegel Textile Corporation*, 484 *F.2d* 1025, 1026-1027 (1st Cir. 1973) (The Flammable Fabrics Act, 15 U.S.C. § 1191 *et seq.*, "makes no provision for private relief for those harmed in accidents involving flammable fabrics" and does not preempt local tort actions to recover damages for such injuries.).

When conflict preemption would leave a tort claimant no redress at law in the state courts, a court should decline to invoke the doctrine. After all, to date this Court has exhibited reluctance to preempt compensatory state procedures when there is no alternative, remedial safety net available to injured claimants. Such a bright-line standard comports readily with the enlightened approach followed by the *Silkwood* Court and the court below. See *Dewey*, 121 *N.J.* at 92, 577 *A.2d* at 1250 ("[A] New Jersey jury could decide that a cigarette manufacturer, rather than an injured party, ought to bear the cost of injuries that could have been prevented with a more detailed warning label than that required under the Cigarette Act.").

The general ruling petitioner seeks would, through mere adoption of approved labeling, insulate a corporation from liability in tort for personal injuries sustained through use of its product. Respondent suggests, contrariwise, that it is inappropriate in the absence of an express statement by Congress to divest state-court plaintiffs in tort actions of all judicial recourse, thereby exempting manufacturers from damages awards. If compliance with FDA regulations or suggestions is an affirmative defense, then by definition it exists in virtually every drug labeling case; victims of inadequate warnings would be altogether unable to avail themselves of the local tort system.[1]

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[1] It may fairly be found, instead, that FDA approval of the labeling in 1963 merely satisfied the conditions laid down by Congress for distribution of Declomycin® in interstate

(Continued on following page)

The safety of the people is the highest law. Cicero, *De Legibus*, III.[2] It must remain so. Therefore, because the FDCA contains no language affording substitute, private relief for those injured from use of prescription medicines, it ought not be given preemptive effect.

If Congress wants to take the extraordinary step of conferring immunity from personal tort actions, it states such intention by statute or legislative history. As Justice Frankfurter observed in *Bethlehem Steel Co. v. New York State Labor Relations Board*, 330 *U.S.* 767, 780 (1947), when this Court considers whether Congress has preempted state law, "[a]ny indulgence in construction should be in favor of the States, because Congress can speak with drastic clarity whenever it chooses to assure full federal authority." See *e.g.* National Traffic and Motor Vehicle Safety Act, 15 U.S.C. § 1392(d); *Farmers Union v. WDAY*, 360 *U.S.* 525, 531-533 (1958) (Pet. 19) (§ 315(a) of the Federal Communications Act of 1934 afforded a radio broadcasting station "immunity" from liability for alleged defamatory statements made in a political speech it transmitted.); compare Comprehensive Smokeless

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(Continued from previous page)

commerce. Neither Congress nor the FDA explicitly or implicitly provided that such approval carried with it as a corollary the proposition that petitioner had met the possibly higher standard of due care imposed by the common law of torts applied under New Jersey law. *Hubbard-Hall Chemical Company v. Silverman*, 340 *F.2d* 402, 405 (1st Cir. 1965). "Ordinarily, state causes of action are not pre-empted solely because they impose liability over and above that authorized by federal law." *English v. General Electric Co.*, ___ *U.S.* ___, ___, 110 *S.Ct.* 2270, 2280 (1990).

[2] *Salus populis suprema est lex*. See also 13 Coke, 139.

Tobacco Health Education Act, 15 U.S.C. § 4406(c). Regulatory agencies, too, can be expected to "make their intentions clear if they intend for their regulations to be exclusive." *Hillsborough*, 471 *U.S.* at 715.

Petitioner misplaces reliance upon the conflict-preemption holding in *Hurley v. Lederle Laboratories Division of American Cyanamid Co.*, 863 *F.2d* 1173, 1179 (5th Cir. 1988) (Pet. 9-10), a decision which runs counter to pertinent preemption considerations laid down by this Court. Compare, *Abbot v. American Cyanamid Co.*, 844 *F.2d* 1108, 1112-1114 (4th Cir.), *cert.* den., 488 *U.S.* 908 (1988) and *Mazur v. Merck & Co., Inc.*, 742 *F.Supp.* 239, 246-248 (E.D.Pa. 1990), as cited in *Feldman* (II), 125 *N.J.* at 140-141, 147-148, 592 *A.2d* at 1188-1189, 1192. Interestingly, while rejecting basic teachings of *Silkwood*, the *Hurley* court declined to deprive the infant plaintiff of all recourse to Texas' tort system. 863 *F.2d* at 1179; see also National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-22(a), (e).

*Papas v. Upjohn Co.*, 926 F.2d 1019 (11th Cir. 1991), petition for *cert.* filed, 59 U.S.L.W. 3825 (U.S. May 29, 1991) (No. 90-1837) also lends no credibility to the arguments of petitioner (Pet. 10-11). *Papas* acknowledges the majority view that the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y, did not preempt state common-law tort suits based on inadequate labeling, but virtually ignores *Ferebee*. *Id.* at 1021 n. 1; compare *Feldman* (II), 125 *N.J.* at 142-143, 592 *A.2d* at 1189-1190. Citing the 1988 Amendments to the Act as indicative of Congress' objective to achieve "Uniformity," 926 *F.2d* at 1025, it also fails to recognize that Congress made no changes to subsections 136v(a) and (b), and that

nothing in the legislative history of those revisions indicates congressional dissatisfaction with *Ferebee*. P.L. 100-532, 100 Stat. 2655 (Oct. 25, 1988). Since the District of Columbia Circuit Court is the primary interpreter of federal regulatory law at the intermediate appellate level, Congress surely would have acted to correct a misconstruction of the Act if one had occurred in *Ferebee*.

The contentions of petitioner call for careful, considerate play of judicial restraint. Without explicit congressional authorization, the subject FDA regulations did not override local tort law. *Cf. Fidelity Sav. & Loan Ass'n. v. De La Cuesta*, 458 *U.S.* 175 (1982) (Rehnquist, [C.]J., dissenting).

## II. PETITIONER OFFERS NO SOUND REASON FOR THIS COURT TO PERMIT IT TO EVADE LIABILITY TO RESPONDENT UNDER NEW JERSEY TORT LAW.

Accusing the New Jersey Supreme Court of "evading" the sweep of the Supremacy Clause, petitioner offers several excuses why it should not have been called to account in a New Jersey court for deliberately marketing a product which caused a young girl to be grossly deformed for life through no fault of her own. Pet. 12 *et seq*. None of its excuses is valid.

### A. The American Cyanamid Company Would Not Have Gone Out Of Business Had Its Lederle Laboratories Division Withdrawn Pediatric Dosage Forms Of Declomycin® From The Market Until A Tooth-Discoloration Warning Had Been Provided.

Petitioner strains all credulity by asserting the possibility that, had pediatric dosage forms of Declomycin®

temporarily been withheld from the market in 1962 and 1963, it somehow would have gone "out of business." Pet. 12-14. During those years Declomycin® was but one of a group of tetracycline-based antibiotics "produced by different drug manufacturers that marketed the drugs under various trade names." *Feldman* (I), 97 *N.J.* at 436, 479 *A.2d* at 377. Besides being marketed in adult dosage forms, Declomycin® was available in pediatric dosage forms – drops, syrup, and oral suspension. *Feldman* (II), 125 *N.J.* at 123, 592 *A.2d* at 1179. This case focuses, then, upon only three pediatric dosage forms of one drug from among "all [the] tetracycline products" manufactured by one division of the American Cyanamid Company. *Feldman* (I), 97 *N.J.* at 438, 479 *A.2d* at 378.

Assuming for sake of argument only the commercial detriment petitioner perceives, in 1965 the FDA obviated all difficulty of that sort by directing drug manufacturers to warn immediately of newly discovered dangers without waiting for the FDA to act. *Feldman* (I), 97 *N.J.* at 459, 479 *A.2d* at 390, citing 30 Fed. Reg. 993-94 (1965) and 44 Fed. Reg. 37,447 (1979). It should be noted further that, in 1972, the FDA required drug manufacturers to place warnings on labels "without waiting for a causal relationship to be established by definitive standards. . . . " 37 Fed. Reg. 16,504 (1972); *cf.* 39 Fed. Reg. 33,230-31 (1974).

### B. It Is Illogical To Presume That The FDA Would Have Instituted An Enforcement Action Against Petitioner Had It Warned About A Known Injurious Propensity Of Declomycin® Without Prior FDA Approval.

Words of the New Jersey Supreme Court written over seven years ago bear recollection: "It would seem

anomalous for the FDA to have prevented a drug manufacturer from advising the public immediately of a newly discovered danger while waiting for FDA approval." *Feldman* (I), 97 *N.J.* at 459, 479 *A.2d* at 390.[3] Yet petitioner persists in contending that it faced a condemnation proceeding had it disregarded the supposed mandate of the FDA not to place a tooth-discoloration warning in the Declomycin® label language. Pet. 14-16. Logic if nothing else suggests otherwise, wherefore rejection of its argument by the state court cannot be faulted. *Feldman* (II), 125 *N.J.* 148-149, 592 *A.2d* at 1192-1193.

Petitioner takes a position predicated upon an unfounded assumption that the FDA would have acted in a manner contrary to the primary goal of its enabling enactment, that is, protection of the consuming public. The power of such an agency to make rules that affect substantial individual rights carries with it the responsibility not only to remain consistent with the governing legislation, but also to employ procedures that conform to the law. *Morton v. Ruiz*, 415 *U.S.* 199, 232 (1974). Assuming for sake of argument only that the regulations in issue actually prevented petitioner from warning of the danger associated with Declomycin® without prior FDA permission and, further, that petitioner honestly believed the regulations precluded any unapproved initiative, this Court should find as did the court below that acceptance

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[3] The dissent of Justice Garibaldi would command more attention had she not joined in this assessment.

of the factual and legal proposals of petitioner would only frustrate the foremost purpose of the FDCA.[4]

## CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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[4] At first trial the Director of Regulatory Agencies Relations for petitioner "explained that it was not necessary to obtain FDA approval before placing a warning on a label, but it was the practice to do so." *Feldman* (I), 97 *N.J.* at 438-439, 479 *A.2d* at 379.

Supreme Court, U.S.
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(4)

No. 91-685

IN THE

# Supreme Court of the United States

OCTOBER TERM, 1991

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LEDERLE LABORATORIES, Division Of American Cyanamid Company,

*Petitioner*,

v.

CAROL ANN FELDMAN,

*Respondent*.

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## ON PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF NEW JERSEY

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## REPLY BRIEF IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI

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We showed in our petition that (1) the New Jersey Supreme Court's decision on important questions of preemption law conflicts with the decisions of two federal courts of appeals, and (2) the state court erred in holding that petitioner could be liable for failing to satisfy a "duty to warn" under state tort law when, at the same time, federal law expressly barred the use of warnings not approved by the Food and Drug Administration ("FDA") *and* the FDA had specifically declined to approve the warning at issue. In opposition to the petition, respondent concedes the first point[1] and virtually ignores the second.

Federal law required the FDA's prior approval of any warning before petitioner could place it on its Declomycin® "label" (a term broadly defined to include other descriptive materials accompanying the distribution of a drug).[2] The state-imposed "duty to

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[1] We argued that the New Jersey Supreme Court's decision in this case conflicts with *Hurley v. Lederle Laboratories Division of American Cyanamid Co.*, 851 F.2d 1536, *modified*, 863 F.2d 1173 (5th Cir. 1988) (Pet. at 9-10), and *Papas v. Upjohn Co.*, 926 F.2d 1019 (11th Cir.), *petition for cert. filed*, 59 U.S.L.W. 3825 (U.S. May 29, 1991) (No. 90-1837) (Pet. at 10-11). Respondent does not contend that *Hurley* and *Papas* are not in conflict with the state court's decision in this case; she merely argues that they are incorrect and should be ignored. Brief in Opp. 12-13.

[2] Contrary to respondent's assertions, Brief in Opp. 14, subsequent changes in federal drug labeling regulations are irrelevant to this case. The question in this case is whether petitioner can be held liable under state law for failing to give a warning barred by federal law; later changes in the federal law do not affect the analysis or the importance of that question, which recurs under a variety of contemporary statutory schemes (as the *Hurley* and *Papas* cases demonstrate). *See* Pet. 3-4 and n.1.

warn," on the other hand, requires drug manufacturers to provide warnings of known or knowable risks, whether FDA has approved or, as here, specifically disapproved such warnings. Petitioner could satisfy the state law duty to warn only by violating the federally imposed duty to use only those warnings that had received FDA approval. In such a situation, federal law must prevail.

In opposing the petition, respondent provides a long dissertation on federal preemption doctrine and argues that FDA's labeling regulations can have no preemptive force because federal law does not expressly provide a private remedy for injuries resulting from the failure to provide warnings. Congress, respondent claims, would not have abrogated a state remedy without explicitly saying that it was doing so, unless it provided a substitute federal remedy. Brief in Opp. 10-12. (This argument also is being made in *Cipollone v. Liggett Group, Inc.*, 893 F.2d 541 (3d Cir. 1990), *cert. granted*, 111 S. Ct. 1386 (1991), *argued*, 60 U.S.L.W. 3278 (Oct. 8, 1991), *restored to calendar for reargument*, Order List (Oct. 21, 1991), and, for this reason alone, the writ should be granted

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Moreover, even though pre-approval of new warnings is no longer required for drugs as a general matter, *but cf. Hurley*, 863 F.2d at 1179 (prior FDA approval is required for warnings given with biologics), current law does not permit a drug manufacturer like petitioner to ignore a determination by FDA that a proposed warning would be inappropriate. *See* 21 C.F.R. § 314.70(c)(2), § 314.71 (supplemental applications for changes in labeling must be filed contemporaneously with making such changes and are subject to the same approval procedures in effect for new drug applications). FDA made just such a determination here. *See* Pet. 5-6.

so that this case can be considered in conjunction with *Cipollone*.)

Respondent, however, misses the pivotal point that this is a case presenting a *conflict* between federal and state requirements, not a case raising the issue whether Congress expressly preempted state law or did so implicitly by "occupying the field" of drug labeling regulation. The presence or absence of a federal remedy simply is not an issue. Here, the standards of conduct imposed by federal law conflict with those imposed by state law. In light of this conflict, the Supremacy Clause bars the state from enforcing its standards of conduct, and the absence of a remedy, federal or state, has no legal significance.

Because respondent ignores this straightforward analysis, her reliance on cases such as *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), is misplaced. In *Silkwood*, unlike here, federal and state law were deemed to be complementary rather than contradictory. The Court noted that even though federal law occupied the field of nuclear safety regulation, such "field preemption" did not preclude an award of punitive damages against an operator of a nuclear fuel facility that released radiation in violation of federal regulations *and* standards imposed by state tort law. Under those circumstances, tort law served to complement federal safety regulations by allowing private plaintiffs to recover punitive damages for breaches of the federal law. The question, therefore, was whether the federal law was nevertheless so comprehensive as to preclude the state remedy, and the Court held that, in part because of the absence of a federal private remedy, it was not.

In this case, unlike *Silkwood*, respondent does not seek redress under state tort law for conduct simultaneously deemed unlawful under federal regulations. To the contrary, the warning she would require was specifically barred by federal law. In a context such as this, the presence or absence of federal remedies has no relevance, because the state law duty, the violation of which might otherwise give rise to the tort remedy, is unenforceable under the Supremacy Clause.

Finally, we respectfully suggest that Congress, and the FDA, know quite well that *salus populi suprema lex*. *See* Brief in Opp. 11 (citing Cicero, *De Legibus*, III). Together they created a comprehensive federal scheme for the regulation of prescription drugs, including the drug involved in this case. The federal regulatory scheme requires FDA to balance risks and benefits and to consider carefully what must appear on each drug's "label." In order to protect the safety of the public in general, FDA struck what it perceived to be the appropriate balance in this case, and petitioner complied with FDA's directive. A hodgepodge of labeling requirements imposed by state law, over the objection of the federal regulators, would not (in the judgment of Congress) contribute to the "salus populi." More importantly, when state law and

federal law conflict, the Constitution makes federal law the *suprema lex.*

Respectfully submitted,

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